

EXHIBIT E

1
2 IN THE UNITED STATES DISTRICT COURT
3 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
4 AT CHARLESTON
5
6

7 DIANNE M. BELLEW, :
8 Plaintiff, : CASE NUMBER
9 v. : 2:13-cv-22473
10 ETHICON, INC., :
11 ETHICON, LLC, and :
12 JOHNSON & JOHNSON, :
13 Defendants.
14

15 TRANSCRIPT OF TRIAL DAY 4

16 MARCH 05, 2015

17 BEFORE THE HONORABLE **JOSEPH R. GOODWIN,**
18 UNITED STATES DISTRICT JUDGE
19

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produced by computer.

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1 PROCEEDINGS had before The Honorable Joseph R.
2 Goodwin, District Judge, United States District Court,
3 Southern District of West Virginia, in Charleston, West
4 Virginia, on March 05, 2015, as follows:

5 (The Jury entered the courtroom at 9:06 a.m.)

6 THE OFFICER: All rise.

7 THE COURT: Good morning.

8 RESPONSE: Good morning, Your Honor.

9 THE COURT: Can you tell that John has been opening
10 court for more than one time?

11 (Laughter.)

12 THE COURT: I trust you had a pleasant evening, if
13 not a necessarily pleasant transition from your place of
14 lodging to here. I knew we could all make it and we all did.
15 I have this theory about -- if I may waste a minute of your
16 time, and, timekeeper, you can deduct this. I have a theory
17 that if the news media goes crazy and says it's going to be
18 awful and you can't possibly move and go immediately to your
19 homes and hide under the bed, that it's not going to be bad at
20 all; that the times that it's really bad is when it catches us
21 all by surprise and we don't even know it.

22 I just -- some of you are old enough to remember when
23 Governor Rockefeller declared a blizzard was coming and we all
24 went to our homes and there was nothing but blue sky.

25 (Laughter.)

—KAMMERER - CROSS BY VIDEO—

1 THE COURT: And he never lived it down. It was and
2 will be remembered by anybody old enough as the Rockefeller
3 blizzard. I don't think there was a quarter of an inch of
4 snow.

5 All right. We're ready to resume. Call your next
6 witness.

7 MR. THOMAS: Your Honor, defendants will continue
8 with the examination of Gene Kammerer.

9 THE COURT: Oh, that's right, we've got
10 cross-examination.

11 MR. THOMAS: Yes, Your Honor. Thank you.

12 THE COURT: Very well.

13 (The videotaped cross-examination testimony of
14 Dr. Gene Kammerer was played for the jury from 9:10 a.m. to
15 9:19 a.m.)

16 MR. THOMAS: That's the cross-examination, Your
17 Honor.

18 THE COURT: Is there any redirect?

19 MR. SLATER: There is none, Your Honor.

20 THE COURT: Any exhibits?

21 MR. THOMAS: No, Your Honor.

22 THE COURT: Call your next witness.

23 MR. ANDERSON: Yes, Your Honor. At this time
24 plaintiffs called Dr. Vladimir Iakovlev.

25 THE COURT: Doctor?

—IAKOVLEV - DIRECT - ANDERSON—

1 THE DEPUTY CLERK: If you'll raise your right hand.

2 (VLADAMIR IAKOVLEV, HAVING BEEN DULY SWORN, TESTIFIED AS
3 FOLLOWS:)

4 THE WITNESS: Yes, I do.

5 THE DEPUTY CLERK: Thank you. Please take the
6 witness stand.

7 (DIRECT EXAMINATION OF VLADIMIR IAKOVLEV BY MR. ANDERSON:)

8 Q. Good morning.

9 A. Good morning. Is it on?

10 THE DEPUTY CLERK: Oh, it's over here. No, it's not
11 on.

12 THE WITNESS: I think you just need to increase the
13 volume.

14 THE COURT: No, we need to get the microphone in
15 front of him.

16 THE DEPUTY CLERK: He has a lapel mic on.

17 THE COURT: Well, somebody else can do that. Have
18 you got it? Okay. Got your own microphone, good.

19 BY MR. ANDERSON:

20 Q. Okay. Take two. Good morning.

21 A. Good morning.

22 Q. What is your -- what is your name, please?

23 A. Vladimir Iakovlev.

24 Q. And what is your occupation?

25 A. I am a medical doctor.

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. Do you have a subspecialty?

2 A. I'm a pathologist.

3 Q. And what is pathology?

4 A. Pathology is laboratory medicine. It's in the lab, in
5 the hospital. Pathologists work in the lab and receive
6 samples from the patients. This would be fluids like blood,
7 like urine, and tissue samples like cells and biopsies. We
8 analyze the samples, we come up with the diagnosis, and we
9 report this diagnosis for further treatment of the patients.

10 Q. Do you have a particular focus within pathology?

11 A. I am an anatomic pathologist.

12 Q. Anatomic pathologist?

13 A. Anatomic pathologist.

14 Q. And what is anatomic pathology?

15 A. Anatomic pathology is the field of pathology where we
16 analyze tissue samples, not fluids like blood, but tissue
17 samples, create cells like Pap smears, tissue samples such as
18 biopsies, or large resections, like a breast resection or
19 stomach resection or we do the whole body, we do autopsy.

20 Q. You are saying resection. What is a resection?

21 A. Resection, when surgeons cut out part of the organ, part
22 of the colon or part of the stomach or from the breast.

23 Q. Are you familiar with a term in medicine known as a
24 "differential diagnosis"?

25 A. Yes.

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. Is that something that you, as an anatomic pathologist,
2 use in your daily practice?

3 A. Yes.

4 Q. Can you please explain that to the jury?

5 A. Differential diagnosis is basic -- basic principle in
6 medicine to arrive at a diagnosis. When the patient comes to
7 the hospital with some problem, medical doctors examine, so
8 they have their differential diagnosis, medical diseases on
9 the differential diagnosis.

10 Q. Go a little slower, if you would, please.

11 A. Multiple diseases are differential diagnosis. The
12 differential diagnosis --

13 THE COURT: I couldn't understand you. I'm sorry.
14 Say it again.

15 BY MR. ANDERSON:

16 Q. Just go a little slower, okay? And a little louder.

17 A. Differential diagnosis is multiple diseases.

18 When the patient comes to the hospital, they present
19 with a problem, and after -- after examination, clinicians
20 have several diseases in their mind which can cause these
21 problems. And then they order tests, including taking
22 samples, and send them to pathology.

23 When it comes to me, I have my differential diagnosis,
24 depending on what I see in the microscope. And then I do my
25 investigation, like medical investigation, and then I narrow

—IAKOVLEV - DIRECT - ANDERSON—

1 down this even further. From many diseases, we go down to
2 one, which is the right one.

3 Q. Is that something that you do every day in your practice
4 as a pathologist?

5 A. Yes.

6 Q. And is that something that you did in arriving at your
7 opinions and your expert conclusions in this matter?

8 A. Yes.

9 MR. ANDERSON: Your Honor, may I approach?

10 THE COURT: You may.

11 BY MR. ANDERSON:

12 Q. Dr. Iakovlev, I'm showing you what has been marked as
13 plaintiff's Exhibit P-2258. Can you please just identify that
14 for the record?

15 A. This is my curriculum vitae.

16 Q. And what is a curriculum vitae?

17 A. This is a description of my career or my education or my
18 work and my publications.

19 Q. Okay. And you have it there in front of you in case you
20 need to refer to it during this part of your testimony, where
21 I'm just going to go through your background and training and
22 education. Okay?

23 A. Okay.

24 Q. Where do you currently work?

25 A. I work at St. Michael's Hospital, that's in Toronto,

—IAKOVLEV - DIRECT - ANDERSON—

1 Canada.

2 Q. What's your current position?

3 A. I am the director of cytopathology and I am an anatomic
4 pathologist.

5 Q. How long have you been at St. Michael's?

6 A. About eight years.

7 Q. And what is cytopathology?

8 A. Cytopathology is the part of anatomic pathology where we
9 examine cells.

10 Q. Slow down a little.

11 Okay. You examine cells. Go ahead.

12 A. Cells. Not larger pieces of tissue, but cells, which are
13 scraped off like Pap smears or aspirated through a fine,
14 really thin needle.

15 Q. Explain to the jury what you do on a day-to-day basis at
16 St. Michael's as an anatomic pathologist.

17 A. As an anatomic pathologist, I examine tissue samples.
18 Surgeons and radiologists and other clinicians take tissue
19 samples from the patient, then they send them to the lab.
20 When we receive them at the lab, we examine them first by
21 naked eye, grossly, and by feeling them with our fingers.
22 Then we take sections from those samples for microscopy, send
23 them to the histotechnologists, they make glass slides like
24 this, and then we examine them under the microscope.

25 Q. Are you familiar with the term clinicopathological

—IAKOVLEV - DIRECT - ANDERSON—

1 correlation?

2 A. Yes.

3 Q. Okay. What is that term to you as a pathologist?

4 A. Clinicopathological correlation is when I correlate
5 medical history, radiological appearance, and my pathology
6 findings. I put everything together, like pieces in jigsaw
7 puzzle, to show the big picture and to arrive with a correct
8 diagnosis.

9 Q. Briefly describe for the jury, please, your education and
10 training that prepared you to work as a pathologist.

11 A. To become a pathologist, one needs to go through medical
12 school. I did my medical training in Russia. At that time
13 the system there was similar to United Kingdom. You can
14 either go directly from high school or you can do first
15 college degree and then apply to medical school. I did my
16 volunteer work at the hospital ward, I attended anatomy
17 scientific society, and I passed my entrance exams with high
18 marks, and I was accepted directly from high school.

19 After graduation of the medical school, it was time of
20 great struggle. That was early '90s. The government didn't
21 have money, didn't care much, didn't invest money in the
22 medical system. And we wanted to build our careers to do
23 research.

24 At the same time I remembered how my mother traveled to
25 Canada in early '80s, so the logical thought was to immigrate

—IAKOVLEV - DIRECT - ANDERSON—

1 to Canada. We applied for immigration and we got our
2 immigration papers in a year.

3 When we came to Canada, we took our licensing exams,
4 medical licensing exams in Canada and United States, and I
5 applied for anatomic pathology residency and was accepted at
6 the University of Manitoba.

7 Q. Where do you hold medical licenses?

8 A. I hold medical licenses in the Province of Ontario,
9 Toronto, and State of Michigan, U.S.A.

10 Q. Are you board certified in any fields?

11 A. Yes. I am board certified for anatomic pathology, by the
12 Royal College of Physicians and Surgeons of Canada, and by
13 American Board of Pathology.

14 Q. How does one obtain board certification, just briefly?

15 A. You submit all your education and training, they evaluate
16 if it's sufficient and then you take exam. If you pass the
17 exam, you obtain your certification.

18 Q. Do you have to retake the board certification test?

19 A. Yes. I have to retake the American Board of Pathology
20 exam every ten years. This was a relatively recent decision
21 because the field was changing so fast that if the
22 pathologists were not updating their knowledge, they would not
23 be able to deliver the same standard of care.

24 Q. Slow down just a little bit if you would.

25 As a current practicing pathologist, are you required

—IAKOVLEV - DIRECT - ANDERSON—

1 to complete continuing medical education courses in your
2 field?

3 A. Yes. That's another initiative, to stimulate
4 pathologists to update their knowledge. The American Board of
5 Pathology, I need to submit every two years specific number of
6 hours of courses and conferences and also meeting exams. And
7 the same thing for Royal College of Physicians and Surgeons of
8 Canada, I have to submit this information every year.

9 Q. Are you currently a member of any professional societies
10 in your field?

11 A. I am a fellow of Royal College of Physicians of Canada in
12 Anatomic Pathology, and I'm a fellow of College of American
13 Pathologists.

14 Q. Do you currently have any teaching responsibilities?

15 A. Yes. I am appointed as the director of laboratory
16 medicine at the University of Toronto, I teach medical
17 students, I teach residents, I teach fellows, I teach graduate
18 students, I also teach cytotechnologists, physiotherapists and
19 pathologists.

20 Q. What do your teaching duties entail?

21 A. For medical residents and medical students and also
22 fellows, I teach them every day handling the cases. When we
23 receive the specimens, we examine them together, and I teach
24 them rating the specimens or rating the slides, and then we
25 have formal sessions every week with residents. We teach them

—IAKOVLEV - DIRECT - ANDERSON—

1 during one-hour sessions.

2 Q. Are those principles of differential diagnosis as well as
3 clinicopathological correlation that you described to the jury
4 something that you teach your students as well as the fellows
5 and residents?

6 A. Of course, because this is the basis of medicine, we
7 teach it from the very beginning.

8 Q. And are those principles that you applied in forming your
9 expert conclusions and opinions in this case that you'll
10 present to the Court and jury today?

11 A. Yes.

12 Q. Have you written articles that have been published in the
13 scientific literature?

14 A. Yes. I published over 20 full-sized papers and over 30
15 abstracts; also presented multiple lectures at national and
16 international meetings.

17 Q. Do any of those articles or abstracts relate to your
18 examination of explanted surgical meshes made out of
19 polypropylene like the Prolift that we are here for today?

20 A. Yes. I published two full papers, three papers had
21 submission, about ten abstracts, and also presented multiple
22 presentations.

23 MR. ANDERSON: Your Honor, at this time plaintiffs
24 would seek to move P-2258 into evidence.

25 MR. THOMAS: No objection, Your Honor.

—IAKOVLEV - DIRECT - ANDERSON—

1 THE COURT: It may be received.

2 MR. ANDERSON: Thank you, Your Honor.

3 (PLAINTIFF EXHIBIT P-2258 WAS RECEIVED IN EVIDENCE.)

4 BY MR. ANDERSON:

5 Q. Now, as part of your daily practice at St. Michael's, do
6 you routinely receive foreign bodies or foreign materials like
7 medical devices that have been removed from patients for which
8 you have been asked to render medical diagnoses and opinions?

9 A. Yes, we routinely receive foreign bodies and medical
10 devices. Foreign bodies can be foreign bodied embedded during
11 trauma, during industrial accidents, and motor vehicle
12 accidents.

13 Q. Slow down just a little, please, for the court reporter.
14 Okay?

15 A. And medical devices also are removed when they fail.
16 This would be breast implants, cardiac valves, hips, and knee
17 implants, as well as surgical meshes.

18 Q. Have those explanted surgical meshes including meshes
19 made of polypropylene for transvaginal repair?

20 A. Yes.

21 Q. Have you received surgically removed Prolift mesh to
22 perform pathological analysis as your role as an anatomic
23 pathologist at St. Michael's?

24 A. Yes.

25 Q. Are these explants, including transvaginal meshes and

—IAKOVLEV - DIRECT - ANDERSON—

1 including the Prolift, typically sent to you by the surgeons
2 who have removed them in the hospital?

3 A. Yes.

4 Q. Why do surgeons send explanted foreign bodies like
5 medical devices and transvaginal meshes to you as an anatomic
6 pathologist for your review?

7 THE COURT: Counsel?

8 MR. THOMAS: It calls for what the doctor -- I object
9 to the question because he asked why the doctors sent things
10 to him --

11 MR. ANDERSON: I can rephrase it, Your Honor.

12 THE COURT: All right.

13 BY MR. ANDERSON:

14 Q. What is the purpose of your -- strike that.

15 In your role as an anatomic pathologist at
16 St. Michael's, what is the purpose of surgeons within the
17 hospital sending to you explanted medical devices like
18 polypropylene meshes from their patients?

19 A. Everything which is removed from the human body needs to
20 be sent to pathology. We document it, describe it, describe
21 gross features, how the device or foreign body looked, and
22 then if we can take microscopic sections, we take microscopic
23 sections and assess what's the state of the device itself and
24 what is the state of the tissue around it, if the device
25 failed on its own or there was another condition like a tumor

—IAKOVLEV - DIRECT - ANDERSON—

1 which made the device fail.

2 Q. At some point in time did I ask you to review materials
3 in this case and to give your expert conclusions with regard
4 to Dianne Bellew?

5 A. Yes.

6 Q. Did you do the same thing in this case that you do on a
7 day-to-day, routine basis as an anatomical pathologist at
8 St. Michael's when you receive explanted medical devices from
9 the surgeons?

10 A. Yes.

11 Q. Were you provided materials to review specific to Dianne
12 Bellew in this case?

13 A. Yes. I received medical records from the clinical chart
14 and I received tissue samples excised from -- from
15 Ms. Bellew's body.

16 Q. Okay. And what surgery were those explanted samples
17 from?

18 A. It was July of 2012, the third surgery.

19 Q. For the record, just briefly summarize your understanding
20 of Ms. Bellew's clinical course for the jury as it relates to
21 the case and as it relates to your opinions in the case.

22 A. Ms. Bellew had placement of Prolift medical device in
23 2009 for bladder prolapse. In about two years, she presented
24 with bleeding and pain during intercourse. Initially, she was
25 treated conservatively for vaginal dryness and atrophy. And

—IAKOVLEV - DIRECT - ANDERSON—

1 this changed symptoms to some degree, but she came back in
2 about a month, and the examination showed that there was
3 palpable mesh which was tender on the left which was creating
4 left-sided pelvic pain, and the decision was to excise the
5 painful area. During surgery, it was found to be sclerotic
6 and hardened. It was excised, which gave some relief of the
7 symptoms, but Ms. Bellew came back, I think in about October,
8 with recurrence of the symptoms. There was more excision done
9 at that time, and, again, there was a period of relief or
10 improvement of the symptoms. But then she came back in a
11 year, and it was the same symptoms. Examination showed more
12 of hardened tender mesh. And then Dr. DeHasse proceeded for
13 large excision.

14 Q. And from that large excision in July, 2012, what's your
15 understanding of how many pieces of Prolift mesh were
16 surgically removed?

17 A. From the original pathology report, there was seven
18 pieces of the mesh removed.

19 Q. How many fragments of the mesh from that surgery were
20 made available for you to analyze?

21 A. Four.

22 Q. And did you analyze all four of them?

23 A. Yes, I analyzed all four.

24 Q. How did you receive the pieces of mesh that you analyzed
25 from Ms. Bellew's surgery in July, 2012?

—IAKOVLEV - DIRECT - ANDERSON—

1 A. They came in a container with formalin.

2 Q. And what is formalin?

3 A. Formalin is basically formaldehyde. It is natural
4 fixative. It preserves tissue. It was discovered about a
5 hundred years ago and became standard preservative for tissue.
6 All those specimens you see in museums are preserved in
7 formalin. You preserve specimens in time. They don't
8 degrade, they don't decompose.

9 Q. And is the use of formalin in order to preserve tissue
10 standard in your industry for the preservation of explants
11 from people's bodies?

12 A. Yes.

13 Q. Other than receiving the container in formalin, what else
14 did you receive with -- if anything, with the surgical pieces
15 when you first received them?

16 A. The chain of custody and medical records.

17 Q. Did you photograph the explanted fragments that you had
18 available for you to analyze?

19 A. Yes.

20 MR. ANDERSON: Okay. Your Honor, may I approach?

21 THE COURT: You may.

22 BY MR. ANDERSON:

23 Q. I'm showing you what has been marked as P-1909. Can you
24 first, please, just identify that for the record?

25 A. This is the gross photograph of the specimen I received.

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. You said gross photograph and gross specimen a couple of
2 times. I just want to make the jury understands what those
3 terms are for a pathologist.

4 What do you mean by gross specimens, please?

5 A. Gross means by naked eye enhanced. Microscopic is what
6 we see in microscopy.

7 Q. Did you take this photograph?

8 A. Yes.

9 Q. Does this photograph that you took fairly and accurately
10 represent the Prolift mesh pieces as you received them?

11 A. Yes.

12 Q. Did you rely on this document in forming your opinions in
13 this case?

14 A. Yes.

15 Q. Is it significant to your opinions in this case?

16 A. Yes.

17 MR. ANDERSON: Your Honor, we would ask that we be
18 able to publish this to the jury and enter plaintiff's P-1909
19 in the record?

20 THE COURT: It may be admitted and published.

21 MR. ANDERSON: Thank you.

22 (PLAINTIFF EXHIBIT P-1909 WAS RECEIVED IN EVIDENCE.)

23 (The document was published to the jury.)

24 BY MR. ANDERSON:

25 Q. Please explain to the jury what we are seeing in

—IAKOVLEV - DIRECT - ANDERSON—

1 plaintiff's 1909 in this photograph, Dr. Iakovlev.

2 A. There is identification of the surgical number, and I can
3 correlate it with the medical information system of
4 St. Michael's Hospital and can trace it and see this specimen
5 is from Ms. Bellew.

6 Also you can see there are four pieces, and please pay
7 attention here. There are blue threads inside this piece. We
8 will come back to these blue threads later.

9 Q. Can you remove the dots for a moment and can you blow up
10 the left-hand piece? You need to tap the screen, I think.

11 A. Yes, we can see the blue threads between the dots.

12 Q. What are those blue threads from, Dr. Iakovlev? What are
13 those blue threads from?

14 A. Those are blue threads of the Prolift device.

15 And another observation here, you see these blue
16 threads are not in line, like this. They have different
17 orientation, shows that mesh is not flat, even from gross --
18 gross appearance.

19 Q. As part of your pathological analysis of these pieces of
20 mesh, what did you do next?

21 A. I examined them with my fingers, I compared them to the
22 normal tissue, which is also fixed in formalin, and I found
23 that these pieces were hardened, and it was much thicker than
24 would be one layer of mesh. And then I submitted these pieces
25 for microscopic examination. I sent them to laboratory

—IAKOVLEV - DIRECT - ANDERSON—

1 technicians to produce histological slides.

2 Q. Did you say pathological slides?

3 A. Histological slides.

4 Q. Histological slides, okay.

5 What does histology or histological slides, what does
6 that mean in your field?

7 A. Histological slides is when the tissue is examined in the
8 microscope.

9 Q. Did you prepare the slides from Ms. Bellew's explanted
10 mesh material in the same manner that you prepare pathology
11 slides in your normal daily practice?

12 A. Yes.

13 Q. Did you prepare the slides in a manner as a standard
14 pathologist would in your field or your industry?

15 A. Yes.

16 Q. Can you please explain the process of preparing pathology
17 slides for the jury as you did from Ms. Bellew's explant.

18 A. When the tissue is submitted to prepare the histological
19 slides, we need to take really thin sections so the light can
20 shine through and I can see it in the microscope. So we take
21 sections like sections of slices of the meat in the deli in
22 the grocery store. We take the sections and these thin
23 slices, then I put on glass slides, and you can see that. So
24 they are very thin, about five microns thick. Now the light
25 can shine through and I can see features inside the tissue.

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. How many slides did you prepare for Ms. Bellew's -- these
2 four explanted pieces?

3 A. 15.

4 Q. Are you prepared today to offer expert opinions and
5 conclusions for the Court and the jury based on your
6 pathological analysis of Ms. Bellew's explanted Prolift mesh
7 and tissue?

8 A. Yes.

9 Q. Will all of your opinions today be stated to a reasonable
10 degree of medical certainty?

11 A. Yes.

12 Q. Have you used your knowledge, training, experience as an
13 anatomical pathologist, as well as your review of her medical
14 records and these specimens in examining Ms. Bellew's
15 pathology and arriving at your opinions here in this case?

16 A. Yes.

17 Q. What methods did you use to analyze Ms. Bellew's
18 pathology specimens that you received in this case?

19 A. I used standard methods of staining and using polarizing
20 light.

21 Q. Okay. First of all, explain to the jury what staining
22 is.

23 A. Staining is using dyes, like for fabric, to dye tissue
24 because tissue is so thin, it's transparent. We cannot see
25 it. So first we need to stain it with dyes, and then we can

—IAKOVLEV - DIRECT - ANDERSON—

1 see it in the microscopy.

2 There is also another role for stains. Some stain
3 stain on the specific structures so we can differentiate what
4 type of cells I'm looking at.

5 Q. Did you use any other standard methods in your industry
6 to analyze Ms. Bellew's explanted tissue to arrive at your
7 opinions today?

8 A. I used polarized light.

9 Q. Okay. Explain to the jury what polarized light on a
10 microscope means in term of analyzing explanted medical
11 devices or explanted mesh.

12 A. Polarized light, I need to use polarized filter. These
13 are like polarizing glasses. These glasses can be used for
14 fishing because when you look at water, the light shines,
15 there is too much light, and it's all in different directions.
16 You can see the surface of the water. But if you use
17 polarizing glasses, it's only one direction of light going
18 through the glasses, and you can see better if you caught the
19 fish. So the polarizing filters are like venetian blinds.
20 They let light in one orientation go through, like venetian
21 blinds.

22 So if we have two filters with the same orientation,
23 placed against each other, the light can go through. But if I
24 take this filter and I turn it, the orientation of filters is
25 perpendicular so the light cannot go through. But if there is

—IAKOVLEV - DIRECT - ANDERSON—

1 object inside, between this filter, which can change
2 orientation, the light, which is perpendicular, turns through
3 the object and then passes through the next filter and I can
4 see it in the microscope.

5 Q. What is the application of that in this particular case,
6 and, that is, using polarized light microscopy to arrive at
7 any of your opinions here?

8 A. It was discovered about a hundred years ago and that
9 using this polarizing filters, we can see objects which are
10 clear or which are foreign, which are synthetic in the
11 microscopy, and it has been used since to identify foreign
12 objects in the histological slides.

13 Q. So did you use histological staining in the preparation
14 of slides as well as light microscopy with the polarized
15 lenses to examine Ms. Bellew's explants for which you are
16 going to offer opinions here today?

17 A. Yes.

18 Q. Okay. After you did the staining of her slides, what did
19 you do next?

20 A. I -- first of all, I need to see the history, analyze the
21 history. I have my differential diagnosis.

22 Q. When you say the history, what do you mean? Review the
23 medical records?

24 A. Yes.

25 Q. Okay. The medical records?

—IAKOVLEV - DIRECT - ANDERSON—

1 A. Medical records, clinical history.

2 Then I examine the slides, stained with different
3 stains. And I could assess if there is mesh only and
4 mesh-related conditions or mesh-related changes in the tissue
5 or there is something else, natural, like a tumor or like a
6 vasculitis, something which would occur without the mesh. And
7 then I examined the polypropylene properties using polarizing
8 light.

9 Q. Did you take photographs of the slides while they were
10 under the microscope?

11 A. Yes.

12 Q. What's on the top of the microscope there?

13 A. This is a camera. I mean this is a standard Canon camera
14 to take pictures. I took pictures exactly the same way as you
15 take pictures.

16 Q. What is the purpose of taking photographs of the slides
17 while they're on the microscope?

18 A. To show it to other people and to document something.

19 Q. Did you bring Ms. Bellew's pathological slides that you
20 prepared here with you today?

21 A. Yes.

22 Q. Are they significant to your opinions in this case?

23 A. Yes.

24 Q. Did you rely upon them in forming your opinions in this
25 case?

—IAKOVLEV - DIRECT - ANDERSON—

1 A. Yes.

2 MR. ANDERSON: Your Honor, could Dr. Iakovlev just
3 step down and show the jury the slides and the types of
4 staining that he did from his slide deck, if he agrees to
5 abide by the court rules of speaking up, facing the court
6 reporter, and continue to make it a Q and A with me?

7 THE COURT: Yes.

8 MR. ANDERSON: Thank you.

9 BY MR. ANDERSON:

10 Q. You may step down. Make sure your mic is still on.

11 A. So these are the 15 histological slides I prepared. And
12 you can see that they are different colors, red and green and
13 brown. The red color is H&E or hematoxylin and eosin stain,
14 we're using stains protein, and the pink color within is scar
15 tissue because it has a lot of protein, a lot of collagen.
16 This is trichrome stain, it uses green color to stain collagen
17 and you can see it's all green. And this brown stain, it
18 stains specific proteins, and I will show them later.

19 Q. What is the significance of -- back up just a little.

20 What is the significance of brown staining in those
21 particular photographs or photographic slides?

22 A. I could identify proteins such as S100, myeloperoxidase
23 and smooth muscle.

24 Q. And what is the significance of identifying S100,
25 myeloperoxidase in these slides?

—IAKOVLEV - DIRECT - ANDERSON—

1 A. S100 stains nerves. I can see nerves easier with S100
2 stain. Myeloperoxidase is a chemical produced by macrophages
3 like immune cells which are coming in to fight this bacteria,
4 foreign bodies. So I can see if the macrophages, they are
5 functioning, they are expressing this chemical to destroy the
6 foreign body.

7 Q. Did you take photographs of her slides, Ms. Bellew's
8 slides while they were on the microscope?

9 A. Yes.

10 Q. And did you bring those photomicrographs with you today?

11 A. Yes.

12 Q. Okay. Why don't you put those down.

13 MR. ANDERSON: Your Honor, if I can --

14 THE COURT: May the witness resume the stand?

15 MR. ANDERSON: That's what I was going to ask you
16 about. He has taken photomicrographs and put them on the
17 boards for the jury. So if he would be allowed to stand in
18 front of the jury and show those, these are plaintiff's
19 Exhibit 1910, and they were included in his report and --

20 THE COURT: Did counsel see them?

21 MR. ANDERSON: Yes, sir.

22 THE COURT: Have you seen those?

23 MR. THOMAS: I have, Your Honor.

24 THE COURT: All right. Yes.

25 MR. ANDERSON: And --

—IAKOVLEV - DIRECT - ANDERSON—

1 THE COURT: There are difficulties with the witness's
2 accent and it is helpful if he faces the court reporter so she
3 can see your mouth as you talk.

4 THE WITNESS: I will.

5 THE COURT: Thank you.

6 MR. ANDERSON: We worked this morning to try and --

7 THE COURT: Yes, Carol? Just a minute.

8 THE COURT REPORTER: If I could just move down there,
9 it would be better.

10 THE COURT: All right.

11 MR. THOMAS: Your Honor, can I move?

12 THE COURT: You absolutely may.

13 MR. THOMAS: Thank you, Your Honor.

14 BY MR. ANDERSON:

15 Q. Are these photomicrographs that you relied upon in
16 forming your opinions?

17 A. Yes.

18 Q. Are they significant to your opinions?

19 A. Yes.

20 MR. ANDERSON: Your Honor, we would seek to move 1910
21 into evidence, please.

22 THE COURT: It may be received.

23 MR. ANDERSON: Thank you.

24 MR. THOMAS: Your Honor?

25 THE COURT: Yes.

—IAKOVLEV - DIRECT - ANDERSON—

1 MR. THOMAS: Some of the exhibits have writing on
2 them. They are not the exact exhibits or the
3 photomicrographs. Things have been added by him as
4 descriptive. I don't think that's appropriate to be received
5 into evidence.

6 THE COURT: All right. When we get to that, make
7 that objection.

8 MR. ANDERSON: And I have a good solution for that,
9 and that is like we have done with some of the PowerPoint
10 slides, we will remove the slides that he has put wording on
11 to be able to explain to the jury. Fair enough?

12 MR. THOMAS: That's fine with me.

13 THE COURT: Very well.

14 MR. ANDERSON: Thank you.

15 (PLAINTIFF EXHIBIT P-1910 WAS RECEIVED IN EVIDENCE.)

16 MR. THOMAS: May I sit over here, Your Honor?

17 THE COURT: Yes.

18 Otherwise, what are the numbers?

19 MR. ANDERSON: Yes, sir. So 1910-Z is what's on the
20 left and 1910-Y is on the right.

21 BY MR. ANDERSON:

22 Q. What is significant about and why did you choose 1910-Z,
23 Dr. Iakovlev?

24 A. This is a microphotograph of one of the pieces over here.
25 So -- this is exactly from the slide and one of the pieces was

—IAKOVLEV - DIRECT - ANDERSON—

1 photographed for these boards.

2 Q. And what is the jury seeing? What type of staining are
3 we using -- did you use on the left-hand pathology slide?

4 A. As I mentioned, this is H&E, hematoxylin and eosin stain.
5 It stains pink color collagen and inflammatory cells purple.

6 Q. What is the significance of the red or pink that we see
7 in the -- in 1910-Z on the left?

8 A. Let me first orient the jurors what they see here. These
9 clear spaces, these are polypropylene filaments because it's
10 like fishing line, it's clear. We cannot see it when it's in
11 the light microscope, it's transparent. But remember those
12 blue threads in the gross specimen? Some of the threads in
13 the Prolift device are colored blue, and you can see them blue
14 here. See these colors? This blue, this blue, and this is
15 blue.

16 Q. Is there anything significant about the orientation of
17 the white and blue fibers as we see it in 1910-Z?

18 A. As you can see, that there is at least three layers of
19 the mesh here. It helps it to identify where the mesh is
20 going, and this yellow line shows layers of the mesh. There
21 are three layers of the folded mesh within this piece, and, as
22 I described, the red color represents collagen. So these
23 three layers are all fused, glued together, cemented together
24 by the scar tissue. It's like plywood. If you have several
25 layers and then you glue them together, they become all as one

—IAKOVLEV - DIRECT - ANDERSON—

1 unit.

2 Q. Do you have an opinion as to whether or not those layers
3 were folded while they were still in Ms. Bellew's body?

4 A. Yes. Because as you can see, scar tissue fills
5 completely the entire structure. This can happen only in the
6 body while tissue can ingrow in all the spaces.

7 Q. Are you familiar with the term "fibrotic bridging"?

8 A. Yes.

9 Q. What does the term "fibrotic bridging" mean to you?

10 A. Fibrotic bridging is when scar tissue -- scar tissue is
11 fibrous tissue -- bridges between filaments, and you can see
12 the entire piece is fully encased in scar. This entire
13 specimen is bridging.

14 Q. Are you familiar with the term "scar plates" and "scar
15 encapsulation"?

16 A. Yes. Scar encapsulation is when something encapsulates
17 the object, foreign object. In this case, you see scar
18 tissues inside the foreign object and outside, encapsulating.
19 And this complex of mesh as a rebar inside the scar is scar
20 plated. This entire structure is scar plated.

21 Q. Are you familiar with the term "mesh contraction"?

22 A. Yes.

23 Q. Is there -- do you see mesh contraction in plaintiff's
24 1910-Z?

25 A. So, as we heard this morning, the filaments themselves do

—IAKOVLEV - DIRECT - ANDERSON—

1 not contract. What contracts is when the scar tissue grows
2 in, it tends to contract. Our body developed this mechanism
3 to minimize the damage.

4 You've probably seen in burn victims when there is
5 scarring and then it contracts the joint, it cannot move. The
6 scar tries to pull together, become smaller.

7 The same thing happens here. When the scar tissue
8 grows in, it contracts. This is physiological. This happens
9 to any scar tissue, contracts and pulls everything together.
10 And you can see that there is this wrinkling which occurred in
11 the body because it's completely fused by the scar tissue.

12 Q. Do you have an opinion to a reasonable degree of medical
13 certainty as to what part of Ms. Bellew's body this explanted
14 piece came from? Do you have an opinion?

15 A. Yes.

16 Q. And what is that opinion?

17 A. My opinion is that it came from the anterior vaginal
18 wall, from between the vagina and the bladder, and from this
19 corner, I can see neuroganglia and nerves.

20 Q. Okay. Let's talk about that term real quickly because
21 it's important. What is neuroganglia?

22 A. Neuroganglia are part of involuntary nerve system which
23 controls blood. We know that all nerves come from the outside
24 into the midline. So they come towards the midline, towards
25 the vagina and the bladder. So I know that this part is

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1 further to the outside, towards the arm of the device, the
2 Prolift device, and this part would be closer to the
3 midportion, where you have enough mesh to fold into this
4 folded structure.

5 Q. Is there anything else significant about the orientation
6 of the fibers on plaintiff's Exhibit 1910-Z? Near the
7 neuroganglia, is there anything significant about the top
8 portion where you were just referring to?

9 A. So, when you have a large device, large sheet, it folds.
10 But when you have just an inch, it curls. So this curling, if
11 it is a narrow arm of tape, occurs on both sides. So this
12 curling on both sides is like a rolling or roping. This is
13 called roping because it forms this round structure.

14 Q. And do you see that depicted in 1910-Z?

15 A. (Indicating.)

16 Q. Indicating to the top of the board?

17 A. Yes.

18 Q. Just for the record.

19 A. Yes, in this part. This is an edge which is curled. So
20 this part would be called roping. So the edge is roped like
21 this. (Indicating.)

22 Q. In your opinion, Doctor, what degree of scarring is shown
23 in the explanted tissue in 1910-Z?

24 A. As I said, this is all scar tissue. This is as hard as
25 it gets. I mean, there is no non-scar tissue in this

—IAKOVLEV - DIRECT - ANDERSON—

1 specimen.

2 Q. And that's the next question. Is there any healthy
3 tissue that you can see in plaintiff's 1910-Z in and around
4 the fibers of that explant?

5 A. Not around the fibers. There is a little corner here,
6 transition, but the mesh was excised right at the scar.

7 Q. Okay. Now, anything else significant about those before
8 we move on to the next board?

9 A. No.

10 Q. Okay. Let's look at 1910-NN and MM.

11 First of all, Dr. Iakovlev, let's explain what the jury
12 is seeing on their left in plaintiff's 1910-NN.

13 A. This is a high magnification of the same section you saw
14 before. I've zoomed in and took high magnification photograph
15 of the mesh filaments and surrounding tissue.

16 Q. Why did you do that?

17 A. To show the changes close up and to help you to identify
18 where the mesh filaments are, because they're clearer. I
19 filled them with yellow color on this. This is exactly the
20 same image but just a copy with yellow color representing mesh
21 filaments.

22 Q. And you have on there foreign body and lymphoplasmacytic
23 chronic inflammation. Let's just go with chronic inflammation
24 in the foreign body part. Why do you have those on the board
25 to the right, 1910-MM?

—IAKOVLEV - DIRECT - ANDERSON—

1 A. As I mentioned before, any foreign body placed in the
2 body or which occurs in the body is recognized by the immune
3 system by the body as foreign. So the body sends white blood
4 cells or macrophages to fight with it, to destroy it. So the
5 foreign body reaction is an immune response and the body sends
6 fighter cells to express all those chemicals, reactive
7 chemicals, to destroy either bacteria or foreign body.

8 Q. Now, what is the relationship between a foreign body
9 reaction and foreign body inflammation?

10 A. It's the same, inflammation, reaction is the same.

11 Q. And, again, in these photomicrographs, do you see any
12 evidence of the chronic foreign body reaction as well as
13 chronic inflammation?

14 A. Yes. Sometimes these terms are used interchangeably.
15 Chronic foreign body reaction includes macrophages which are
16 large cells. They look kind of purple. Also, when they come
17 to the object and they feel that they cannot destroy it as one
18 by one, they try to merge together and form a large
19 multinucleated cell, so because the large cells can absorb
20 larger objects and you can see it here. This is a
21 multinucleated giant cell. This is multinucleated giant cell.
22 This is multinucleated cell. There are multiple nuclei. This
23 is the same macrophage but it's like a battalion of them
24 joined together in an effort to destroy the foreign body.

25 Q. Is the inflammation that we see in 1910-NM [sic], is any

—IAKOVLEV - DIRECT - ANDERSON—

1 of that inflammation transient or temporary?

2 A. Absolutely not. The foreign body reaction will stay in
3 the body as long as foreign body stays in the body, until the
4 foreign body is either destroyed or removed.

5 Q. Do you have an opinion to a reasonable degree of medical
6 certainty, based upon your knowledge, training and experience,
7 all the medical records you reviewed in this case, the
8 specimens you reviewed, and the specimens that you reviewed as
9 a pathologist at St. Michael's, as to whether or not
10 Ms. Bellew's Prolift mesh caused the chronic foreign body
11 reaction and chronic inflammation that we see in plaintiff's
12 Exhibit 1910-NM -- NN?

13 A. Yes.

14 Q. And what is that opinion?

15 A. My opinion is that the mesh placed in Ms. Bellew's body
16 caused this foreign body reaction.

17 Q. Did it cause a chronic inflammation?

18 A. Yes, it caused chronic inflammation.

19 Q. Did you rule out other causes of the chronic
20 inflammation, the chronic foreign body reaction, and any other
21 condition that could cause -- well, first of all, let me go
22 back a minute.

23 What is the structure on the top right?

24 A. This is a nerve.

25 Q. Okay.

—IAKOVLEV - DIRECT - ANDERSON—

1 A. So this nerve goes around the filament, and you can see
2 it's pinched here between the scar tissue and mesh filament.
3 Also, seeing a nerve in the tissue means that the tissue can
4 sense pain because without the nerves, it would feel nothing.

5 Q. You've heard the term "pinched nerve" in medicine. Is
6 that what we have in 1910-NN?

7 A. You can see the shape of the nerve, how it is all
8 squished here.

9 Q. What's the result to a patient of a pinched nerve in the
10 tissue surrounded by scar tissue?

11 A. It would cause pain.

12 Q. Do you have an opinion to a reasonable degree of medical
13 certainty as to whether this nerve that is pinched in
14 plaintiff's 1910-NN caused pain in Ms. Bellew?

15 A. Yes.

16 Q. And what is that opinion?

17 A. My opinion is that this deformation is likely to cause
18 pain.

19 Q. As part of your coming to your expert conclusions, did
20 you rule out any other causes of the chronic foreign body
21 reaction, the chronic inflammation, or the pinched nerve as we
22 are seeing in these photos?

23 A. Yes.

24 Q. What did you do to rule out other causes?

25 A. Well, when I examined the specimen, I considered all

—IAKOVLEV - DIRECT - ANDERSON—

1 possibilities --

2 Q. Talk a little bit slower if you could, please.

3 A. I considered all possibilities. Is there a natural
4 condition which could cause all these changes, is there
5 another foreign body which could cause all these changes, and
6 I did not see anything. I saw just Prolift mesh and tissue
7 reaction to it.

8 Q. Did you rule out any other disease conditions?

9 A. Yes. I didn't see, as I mentioned, vasculitis, cancer,
10 or any other systemic conditions.

11 Q. Okay. Now, anything else before we leave these?

12 A. Well, since we were talking about nerves, I wanted to
13 approach how we could sense pain. There are two ways of
14 sensing pain.

15 Q. Okay. What are those?

16 A. Either we have pinched nerve, nerve itself, or we feel
17 pain through receptors, the receptors are irritated. We have
18 pain receptors but we also have other receptors like
19 temperature or vibration. Pain receptors, they send signals
20 of pain only. Other receptors, they can send different
21 signals. Like for temperature, when we feel warm, we feel
22 warm, but when there is too much heat, we feel it as pain, as
23 burning pain. So if the receptors are very much irritated, we
24 can feel it as pain.

25 Now, in the inflamed area, the receptor sensitivity

—IAKOVLEV - DIRECT - ANDERSON—

1 goes up, they become sensitive. It's like a pimple or like an
2 inflamed area. It may not hurt if we don't touch it or move
3 it, but the receptors are sensitized already. Once we touch
4 it or move it, we feel pain. And if there is a lot of
5 inflammation, we can feel pain at rest, it hurts. An inflamed
6 knee can hurt or inflamed wound can hurt.

7 Q. Do you have an opinion, Doctor, as to whether or not the
8 inflamed area around -- first of all, did you see these
9 inflamed areas in other pathological specimens that you looked
10 at from Ms. Bellew?

11 A. This inflammation was surrounding all filaments. The
12 entire mesh area was an inflamed area. So it wasn't just this
13 small area. You can imagine the device, and the entire device
14 is inflamed. It's a large area of inflammation.

15 Q. Okay. Do you have any other slides with you regarding
16 nerve damage or nerve entrapment for Ms. Bellew?

17 A. Yes.

18 Q. Okay. I think those are 1910-BBB and 1910-AAA.

19 You talked to the jury a little earlier about the
20 different types of staining. I think you said the first one
21 was H&E; is that correct?

22 A. Yes.

23 Q. And what is the staining that they see here?

24 A. This is the brown stain, and I ordered my lab to do S100
25 stain. S100 stain stains nerves. I could see and show nerves

—IAKOVLEV - DIRECT - ANDERSON—

1 easier with this stain.

2 Q. Okay. Let's look at the BBB there, 1910-BBB, and explain
3 what you're talking about to the jury.

4 A. So, as before, the clear spaces are spaces of the
5 filaments of the Prolift device, removed from Ms. Bellew's
6 body. In this image, it's the same image, a copy. The empty
7 spaces of polypropylene filaments are filled yellow and the
8 brown color shows nerves in the tissue.

9 Q. What is the significance of findings of the nerves in
10 this as it relates to any clinical pathological correlation
11 with Ms. Bellew's pain symptoms?

12 A. Well, first of all, just by orientation.

13 Q. By orientation, did you say?

14 A. Orientation.

15 Q. Okay.

16 A. And then the nerves, I can identify that this part of the
17 nerve was further away from the midline, from the center.
18 Because, as I explained before, the nerves are coming from
19 outside into inside, so they come out like this and then they
20 go and innervate the vagina and the bladder. So this piece of
21 mesh was oriented like this, in more lateral or further
22 outside position. This part was consistent with arm of the
23 Prolift device. And you can see that there are a number of
24 nerves in this arm of the Prolift device. Some of them are
25 straight.

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. Is that a normal appearance, as long as they're straight?

2 A. Yes, this would be normal appearance. And some of them
3 are bent, and some of them are severely distorted by the
4 Prolift mesh filaments.

5 Q. Explain what you mean by that.

6 A. It would be easier if I showed the blowup and
7 magnification of this area.

8 Q. Okay. Is that 1910-ZZ? Yes.

9 A. Yes. 1910-ZZ and --

10 Q. 1910-L?

11 A. L.

12 Q. Okay.

13 A. So 1910-ZZ is magnification of an area. 1910-BBB,
14 high-powered view.

15 Q. Explain what the jury is seeing there.

16 A. This end of the nerve, the nerve fibers are oriented
17 here, and now we can see that the nerve fibers are indicated
18 here as perpendicular.

19 Q. Is that the area that looks like a fist?

20 A. Yes.

21 Q. Okay. Explain what that is, please.

22 A. The mesh -- the nerve is distorted by the mesh and it
23 forms this bulbous enlargement and changed the course
24 orientation, and then further down, this nerve is more
25 severely distorted, and the fascicles, the particles inside of

—IAKOVLEV - DIRECT - ANDERSON—

1 the nerve, are being separated in the scar tissue.

2 Q. What is the significance to a patient when the fascicles
3 of the nerve have been separated like they are here around the
4 mesh fiber?

5 A. This is a pathological process which forms traumatic
6 neuroma.

7 Q. What is traumatic neuroma?

8 A. Traumatic neuromas form when the nerve is distorted or
9 when it continues to grow in the scar tissue and it hits an
10 obstacle, it cannot grow further, and what happens when it
11 hits the obstacle, the fascicles separate, and then they kink
12 together and then it forms this bulbous enlargement like a
13 pseudotumor.

14 Q. In your opinion, what was the clinical impact on patient
15 safety to Ms. Bellew with regard to these distorted nerves and
16 the separated fascicles that we see in 1910-ZZ?

17 A. It's well established that traumatic neuromas are
18 severely painful lesions. And it wasn't just one. I found
19 several traumatic neuromas in the specimens I removed from
20 Ms. Bellew.

21 This is another one, and you can see it has even more
22 severe inflammation, separation of the fascicles, and the
23 fascicles are all in scar tissue, and this is the larger side
24 of the nerve which is distorted and forms traumatic neuroma.

25 Q. And, again, do you have an opinion as to whether or not

—IAKOVLEV - DIRECT - ANDERSON—

1 all of these specimens that you looked at that we saw grossly
2 on the screen and that now we're looking at microscopically
3 were removed during that July, 2012, explant in an area where
4 Ms. Bellew had complained of pain? Do you have an opinion on
5 that?

6 A. Yes.

7 Q. And what is it?

8 A. It corresponds --

9 Q. Sorry.

10 A. Yes. It corresponds to the location of the pain, the
11 description of the scarred firm mesh, and I concur with the
12 clinical symptoms, with the morphological findings.

13 Q. You said morphological? Explain what morphological
14 findings are, please.

15 A. Morphology is the science of anatomy and histology, is
16 what it is, using microscope and gross appearance.

17 Q. Okay. Go ahead.

18 A. And I found multiple deformations of the nerves, forming
19 traumatic neuromas, excising all the particles of the specimen
20 and I can measure that. There can be more of these lesions in
21 the remaining mesh.

22 Q. Okay. Now, if we could, let's look at plaintiff's
23 Exhibit 1910-KKK and 1910-CC.

24 And, first of all, let's explain to the jury, after you
25 get that one up there, what they're seeing in 1910-KKK.

—IAKOVLEV - DIRECT - ANDERSON—

1 A. This image, it's the same brown type of staining, but I
2 ordered my lab to do smooth muscle stain. It stains smooth
3 muscle of bladder wall, the muscle which contracts during
4 urination.

5 And in this image I filled polypropylene filaments with
6 yellow color so you can orient. All this tissue is scar
7 tissue.

8 Q. Is that the light brown area in between the yellow that
9 you're referring to?

10 A. Yes. There is some areas which are brown. It's blood
11 vessels in the scar tissue because they also have smooth
12 muscle inside the vascular wall.

13 Q. So if this was an H&E staining, this hematoxylin and
14 eosin, what would the light brown color stain, what color
15 would it stain?

16 A. This would be all pink. The entire area would be pink.

17 Q. Okay. Now, you have these thick bundles of smooth
18 muscle. Explain to the jury what you're referring to there
19 and how it relates to the mesh.

20 A. So to see smooth muscle, I ordered smooth muscle stain,
21 and you can see sharp distinction. This part was scar, and
22 this part was smooth muscle of the bladder.

23 Q. Explain to the jury the -- what smooth muscle is in terms
24 of our body.

25 A. Smooth muscle is muscle inside our organs like bowel,

—IAKOVLEV - DIRECT - ANDERSON—

1 contract bowel, like bladder, when it contracts, we urinate,
2 so this is muscle of the bladder.

3 Q. So you're pointing to 1910-KKK. Do you have an opinion
4 as to whether or not this specimen shows Ms. Bellew's mesh up
5 against the detrusor muscle or the smooth muscle of her
6 bladder?

7 A. Yes.

8 Q. Do you have an opinion as to whether or not in 1910-KKK,
9 it represents pathological findings that would be consistent
10 with any urinary symptoms?

11 A. Yes.

12 Q. And what is that opinion?

13 A. My opinion is that the scar tissue and the mesh were
14 interfering with the smooth muscle of the bladder.

15 Q. And what are we seeing in 1910-CC?

16 A. This is H&E stain, hematoxylin and eosin, as before.
17 This is a blow-up picture of that corner of the -- of the
18 Exhibit Z. This is this area, enlargement. As I mentioned
19 before, it contains neuroganglion. Ganglia is like a center
20 where nerves of the involuntary nervous system connect. This
21 is the ganglia. So if I see the ganglia, I know that the
22 nerves, which are connecting to it, are going into the
23 bladder. So if we look between the vagina and the bladder,
24 some nerves go into the vagina and they innervate the vagina.

25 Q. What do you mean by innervate? What does that term mean?

—IAKOVLEV - DIRECT - ANDERSON—

1 A. They shoot their endings into the vagina so the vagina
2 can feel and the muscle of the vagina can contract.

3 Q. Okay. Go ahead, please.

4 A. And then other nerves which are connecting through the
5 neuroganglia, they go into the bladder, and we feel urge to
6 urinate through work of these ganglia and nerves, and we also
7 urinate, the bladder contracts, through work of these ganglia
8 and nerves.

9 Q. Anything else significant about these that you wanted to
10 share with the jury?

11 A. You can see that these nerves are also deformed. There
12 are four. The mesh was interfering with bladder innervation.
13 It was interfering with the nerves which were going into the
14 bladder.

15 Q. In addition to causing urinary problems for the patient,
16 would -- to your opinion, would the scar tissue that we see in
17 CC surrounding the nerve have any implications for
18 Ms. Bellew's condition?

19 A. Yes. Because, as we mentioned before, scar tissue adds
20 stiffness and hardness of the folded mesh.

21 The second significance is that scar tissue entraps
22 nerves and pinches them. So the nerves here are entrapped and
23 pinched between scar tissue and the mesh filaments.

24 Q. Can that cause chronic pelvic pain in patients?

25 A. Yes.

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. Do you have an opinion as to whether or not the
2 entrapment of the nerves that you've seen and the pathological
3 symptoms here were caused by the Prolift mesh?

4 A. Yes.

5 Q. Do you have an opinion as to whether or not the Prolift
6 mesh caused chronic pain for Ms. Bellew?

7 A. Yes.

8 Q. And what is that opinion?

9 A. My opinion is that mesh -- Prolift mesh device and tissue
10 reaction to it caused pain for Ms. Bellew.

11 Q. Do you have an opinion as to whether or not the Prolift
12 mesh caused chronic dyspareunia or sexual problems and sexual
13 pain for Ms. Bellew?

14 A. Yes, I have opinion. This pain --

15 Q. Go ahead. What's that opinion?

16 A. This pain symptoms, dyspareunia, has the same basis,
17 because it's the same pain, with external mechanical stimuli,
18 so the mesh and tissue reaction to mesh caused dyspareunia for
19 Ms. Bellew.

20 Q. And do you have an opinion to a reasonable degree of
21 medical certainty as to whether or not the pathological
22 analysis you've done have shown that Ms. Bellew's urinary
23 symptoms are due -- urinary problems are due to Prolift?

24 A. My pathological findings show that there was interference
25 with urinary function.

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. And as to the specific problems that this scar tissue
2 would have caused to her urinary symptoms, do you have an
3 opinion on that or would you defer to a urologist?

4 A. Specifically what was the urinary symptoms? I would have
5 to defer to urologist.

6 Q. Okay. Ready to take those down?

7 Okay. Doctor, handing you what has been marked as
8 plaintiff's Exhibits P-1910-G and P-1910-M. Please explain to
9 the jury what we're seeing in these two images.

10 A. These are very high magnification images of polypropylene
11 filaments. When the filaments are cut like salami, we look at
12 them from the cut surface. If you imagine salami and then
13 it's cut, so this is the filament, very high magnification,
14 about a thousand times magnification. As I mentioned before,
15 polypropylene is like fishing line, it's clear, so in the
16 microscope, it appears clear, we do not see it. And the
17 tissue around it --

18 Q. What are we seeing, the pink and the purple there in the
19 tissue around the polypropylene fiber?

20 A. This is chronic foreign-body-type inflammation
21 surrounding the filament.

22 Q. And what is this -- out where you have a line going to
23 the degradation bark, explain what you're trying to show the
24 jury there, please.

25 A. If you allow me to --

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. Sure.

2 A. -- take another exhibit.

3 Q. Sure.

4 A. I brought this slice of wood which was cut with a chain
5 saw just to explain some things.

6 So the mesh filament is like a tree trunk. And when we
7 section it, now we're looking at the section like this. So
8 the core of the wood is homogenous, solid like the core of the
9 filament, but then there is a bark tree [sic] around the tree
10 trunk.

11 Q. What is the significance of that cracked outer layer that
12 we're seeing in 1910-G?

13 A. This is the bark layer or outer layer of the degraded
14 polypropylene. It's the same wood but because it was exposed
15 to the outside environment, it's all cracked. It has all
16 these crevices, cracks, and cavities. The same thing happens
17 with the polypropylene. When it's exposed to the body
18 environment, it cracks and forms these cavities, and the
19 histological dye, it gets trapped in it so it sticks in
20 between. It's like clothing. The dye gets in between the
21 fibers in the clothing and that's why it stains. The
22 non-degraded polypropylene is solid, so it cannot be stained.

23 Q. What is the significance to the patient in terms of the
24 tissue reaction in and around the degraded bark as we're
25 seeing in 1910-G?

—IAKOVLEV - DIRECT - ANDERSON—

1 A. So, the tissue reaction, as we discussed before, is
2 designed to destroy foreign bodies. So all these macrophages,
3 they produce chemicals to oxidize, to destroy foreign body.
4 That's what happens. Polypropylene oxidizes and degrades in
5 the body. Then --

6 Q. What is the impact to the patient as a result of this
7 degrading of the polypropylene in the body?

8 A. As you can see, the bark peeled off here, it cracked
9 here, while the central core didn't crack. So the outer --
10 the outer bark became brittle, hardened. We know that if the
11 material is flexible, it would flex. If the material is
12 harder, it will crack. You just bend it more, it will crack.
13 And without bending, when it dries up inside, when there is
14 force inside, it pulls it and it cracks. It's like dry lips
15 or something which is drying and it cracks. It -- it has
16 cracks on the surface. So this is continuous tube-like
17 sheaths around all filaments in the mesh. And this is a tube
18 which is hardened, and the entire mesh becomes stiffer and
19 harder.

20 Q. Do you have an opinion as to whether or not the Prolift
21 mesh that was implanted in Ms. Dianne Bellew degraded?

22 A. Yes.

23 Q. And what is that opinion?

24 A. My opinion is that the polypropylene of the Prolift
25 device degraded while in the body of Ms. Bellew.

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. Do you have an opinion as to whether or not the degraded
2 polypropylene in Ms. Bellew caused an increased inflammatory
3 response?

4 A. Yes.

5 Q. What is that opinion?

6 A. We all know that if a material doesn't degrade, like
7 high-quality stainless steel hips, there is no degradation,
8 and then the inflammatory reaction goes away. No degradation,
9 no reaction. When there is degradation, it's like a feeding
10 frenzy. There are pieces which go into the tissue and they
11 feed this inflammatory reaction. It's like birds, when you
12 feed them, more and more come.

13 Q. What is the jury seeing in 1910-M that you put up here?

14 A. This is the polarization technique. This is exactly the
15 same filament.

16 Q. Did you say polarization?

17 A. Polarization.

18 Q. Is that those lenses you were talking about when you go
19 fishing?

20 A. Yes.

21 Q. Okay. Tell us about that.

22 A. So, to take this photograph, I turned polarizing filter
23 and the light was blocked. This light of this area is dark.
24 Because tissue doesn't polarize much of the light, it doesn't
25 change orientation. If it's blocked, it's blocked. However,

—IAKOVLEV - DIRECT - ANDERSON—

1 polypropylene changes orientation.

2 Q. Changes the orientation of the light?

3 A. Of the light.

4 Q. Okay.

5 A. It's called polarization. So the light goes through the
6 filter, hits polypropylene, changes orientation, and then
7 processes through the second filter.

8 Q. So fiberoptic technology, is that where light is passing
9 through something like polypropylene?

10 A. Yes.

11 Q. Is it the same idea?

12 A. Yes.

13 Q. Okay. Doctor, what did you do to rule out whether or not
14 there was something else that may have caused the cracking
15 around the degraded core? Let me ask it a little bit
16 differently.

17 Did you do anything to rule out whether or not this
18 cracking, cracked outer layer, was something other than
19 polypropylene associated with the fiber?

20 A. Yes.

21 Q. Okay. What did you do to rule out that it was something
22 else other than polypropylene that we're seeing here?

23 A. First of all, I used polarization because this is
24 standard technique, we use polarization --

25 Q. When you say "we," are you talking about pathologists use

—IAKOVLEV - DIRECT - ANDERSON—

1 it?

2 A. Pathologists.

3 Q. Okay. Go ahead.

4 A. If it lights up, it's foreign body or crystals.

5 As you can see here, all tissue around is dark. There
6 is very little light going through collagen. Collagen is the
7 strongest polarizing protein in the body. When the entire
8 tissue is fixed in formalin, it's cross-linked in formalin,
9 and this is as bright as it gets for all human proteins fixed
10 in formalin. And you can see the difference between
11 polypropylene and the strongest polarizing protein fixed in
12 formalin.

13 Q. Do you have an opinion as to whether or not the
14 degraded -- what you have depicted as degraded polypropylene,
15 this cracked outer layer, is biologic material like protein or
16 polypropylene?

17 A. Yes, I do.

18 Q. What is that opinion?

19 A. It is not biologic polypropylene -- it's not biologic
20 material. It is synthetic polypropylene.

21 Q. Did you do anything to rule out whether or not the
22 formalin that Ms. Bellew's explant samples came in had
23 anything at all to do with the degradation bark in the cracked
24 outer layer?

25 A. Yes, I did.

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. What did you do?

2 A. I took new slices, I put them in formalin, kept them in
3 formalin for up to four months, and then loaded them in the
4 same machine, with the same samples, St. Michael's Hospital, I
5 went through all those chemicals, and then through the same
6 staining, and I did not see degradation of polypropylene after
7 four months of fixation in formalin, and the same process and
8 chemicals and temperature changes.

9 Q. Did you use operating procedures that are standard in
10 your industry to conduct this formalin testing on pristine
11 mesh that had never been implanted in a body?

12 A. Yes, they were loaded exactly with the same specimens.

13 Q. And are those standard operating procedures used at your
14 hospital at St. Michael's and the University of Toronto?

15 A. Yes.

16 Q. Now, what else do you have there? Do you have another
17 slide or two and then we can finish up here?

18 This is 1910-P. Please tell the jury what we're seeing
19 in 1910-P.

20 A. As you remember, those blue threads I showed on gross
21 photograph, and also on histological images, these blue
22 threads are manufactured with additional blue dye. When we go
23 to really high magnification, this blue -- this blue dye looks
24 like blue granules.

25 Q. And that's the blue fibers that we see running through --

—IAKOVLEV - DIRECT - ANDERSON—

1 the jury has seen the Prolift mesh. Those would be those blue
2 fibers?

3 A. Yes.

4 Q. Okay.

5 A. So this is cross-section of clear filament. And this is
6 cross-section of blue filament. So since the granules were
7 embedded during manufacturing in polypropylene, they are like
8 internal markers of polypropylene. You can see granules here
9 in the filament. You can see granules --

10 Q. Why is that significant to your opinions with regard to
11 degradation and the outer layer being polypropylene?

12 A. It is significant because this is internal marker. If I
13 see blue granules, it means it's polypropylene which was
14 manufactured, even before it was implanted in the body. I did
15 not see blue granules beyond the surface. They were in the
16 non-degraded core of the filaments, they were present in the
17 degraded bark, they were mainly present deeper inside, and
18 then they degrade towards the surface, and they were not
19 present in the tissue.

20 Q. Okay. All right. Before we -- before we sit down,
21 plaintiff's Exhibit 1910-CC, is that -- where you put some
22 arrows and yellow spots, just for the record purposes, is that
23 the same image that is in plaintiff's Exhibit 1910-EE?

24 A. Yes.

25 Q. Okay. Thank you.

—IAKOVLEV - DIRECT - ANDERSON—

1 Now, I think you can resume the stand now, Doctor.

2 Anything more about this image?

3 A. No.

4 Q. Okay. I see you brought your microscope with you.

5 THE COURT: Wait just a second.

6 MR. ANDERSON: Yes, sir. I'm sorry.

7 THE COURT: Go ahead, Mr. Anderson.

8 MR. ANDERSON: Sorry. Thank you, Judge.

9 BY MR. ANDERSON:

10 Q. I see you brought your microscope with you today. You
11 had been talking about this polarized light microscopy. Are
12 you prepared to at least show the jury one example of that on
13 one slide before we are through here today?

14 A. (Nods head.)

15 Q. Okay. Did you bring something with you to show them?

16 A. Yes, I brought those slides.

17 Q. Okay. May I approach, Your Honor?

18 THE COURT: You may.

19 MR. ANDERSON: Thank you.

20 BY MR. ANDERSON:

21 Q. What is the jury seeing -- I will let you get oriented.
22 Let me know when you're ready.

23 A. So, this is the same slide I showed you before, the slide
24 I took pictures of for the boards. And now I put live slide
25 in the microscope and I am projecting image from this camera.

—IAKOVLEV - DIRECT - ANDERSON—

1 Q. Okay. And so you were saying that you wanted to use
2 light microscopy. Are those the lenses that you have in your
3 hand?

4 A. Yes. This is one lens.

5 Q. Okay.

6 A. And one lens is in between the camera and the object
7 here.

8 Q. Please demonstrate what the significance would be of
9 using the polarized images for -- in order to identify foreign
10 material.

11 A. So I'm going to place this filter in the microscope, and
12 you can see that all tissue goes dark. Polypropylene --

13 Q. What are the light spots that we're seeing?

14 A. This is polypropylene.

15 Q. So is that light being projected down through the image
16 and bending through the polypropylene?

17 A. Yes.

18 Q. And what's all the black area?

19 A. This is all tissue, human tissue, fixed in formalin.

20 Q. Why is that significant to your opinions in this case, if
21 at all?

22 A. That's how I identify what is polypropylene and what is
23 human tissue.

24 Q. Okay. You can shut that down.

25 Now, Doctor, with my help, did we prepare a slide today

—IAKOVLEV - DIRECT - ANDERSON—

1 regarding your clinicopathological findings as they relate to
2 your opinions related to Ms. Bellew?

3 A. Yes.

4 THE COURT: All right. You may proceed.

5 MR. ANDERSON: Thank you.

6 BY MR. ANDERSON:

7 Q. So, I want to go through these clinicopathological
8 findings real quickly if I could, Doctor.

9 You see there mesh folding and roping, scar
10 encapsulation, scar plate, fibrotic bridging, mesh
11 contraction, chronic foreign body inflammation, nerve
12 entrapment and deformation, traumatic neuroma, and degradation
13 of polypropylene fibers.

14 Do you have an opinion to a reasonable degree of
15 medical certainty based upon your knowledge, training and
16 experience, your work as a pathologist for 15 years, your work
17 on this case reviewing the medical records of Dianne Bellew,
18 your work reviewing the explanted specimens from Dianne
19 Bellew, as to whether or not all of these clinicopathological
20 findings occurred in Ms. Bellew?

21 A. Yes.

22 Q. What's that opinion?

23 A. My opinion is that all these morphological changes were
24 related to mesh placement in the body and body reaction to it.
25 And these changes caused these clinical symptoms.

—IAKOVLEV - CROSS - THOMAS—

1 Q. Can you list those clinical symptoms, please?

2 A. Chronic pelvic pain, chronic painful sexual intercourse
3 which is dyspareunia, and change of urinary symptoms.

4 Q. Okay.

5 MR. ANDERSON: That's all I have for the direct, Your
6 Honor.

7 THE COURT: All right. That makes a good time for us
8 to take a morning break before cross-examination.

9 Ladies and gentlemen, during the break, do not
10 discuss the case among yourselves or permit anyone to discuss
11 it with you. Don't use any social or digital media for any
12 purpose about this case. I'll call you back in 15 minutes.

13 The witness may step down. Please don't talk to
14 anybody during the break. All right.

15 THE OFFICER: All rise.

16 (The Jury left the courtroom at 10:34 a.m.)

17 (A recess was taken at 10:34 a.m.)

18 (The jury entered the courtroom at 10:52 a.m.)

19 THE COURT: Thank you, ladies and gentlemen.

20 If the witness would retake the stand,
21 cross-examination is now in order.

22 MR. THOMAS: Thank you, Your Honor.

23 (CROSS EXAMINATION OF VLADIMIR IAKOVLEV BY MR. THOMAS:)

24 Q. Hello, Doctor.

25 A. Hi.

—IAKOVLEV - CROSS - THOMAS—

1 Q. As a part of your work in this case you've not examined
2 Mrs. Bellew; correct?

3 A. Yes, that's correct.

4 Q. And you've not talked to Ms. Bellew about the case?

5 A. That's correct.

6 Q. And you've not talked to any of her treating physicians;
7 correct?

8 A. That is correct.

9 Q. And not reviewed any of their depositions. Am I right?

10 A. That's correct.

11 Q. And you have no opinion in this case about whether the
12 surgeon placed the Prolift properly at the time of the July,
13 2009, implant; correct?

14 A. I don't have an opinion.

15 Q. You know the implant date was July 9, 2009?

16 A. Yes.

17 Q. And you know that the explant date of the mesh that you
18 analyzed was July 12, 2012?

19 A. That's correct.

20 Q. So, the mesh that you looked at was in Ms. Bellew for
21 about three years; correct?

22 A. That's correct.

23 Q. And at the time of the explant surgery, the surgeons sent
24 the explants that you reviewed to the hospital pathology
25 department, didn't they?

—IAKOVLEV - CROSS - THOMAS—

1 A. That's correct.

2 MR. THOMAS: Your Honor, may I approach?

3 THE COURT: You may.

4 BY MR. THOMAS:

5 Q. Doctor, I've handed you what's been marked as
6 Defendant's Exhibit 10041. And you recognize this as
7 the surgical pathology report for Northwest Medical
8 Center which is the pathology department that received
9 Ms. Bellew's mesh following her surgery?

10 A. That's correct.

11 Q. And the pathologists at the Northwest Medical Center did
12 not conduct the same kind of analysis that you did, did they?

13 A. You're correct. They received, documented, and sent the
14 specimen to Steelgate.

15 Q. At least at that time, the pathologist didn't think it
16 necessary to make slides and analyze them for the purposes
17 that you did. Fair?

18 A. I don't know.

19 Q. But you haven't seen any pathology report analyzing
20 Ms. Bellew's slides beyond what you've done, have you?

21 A. Could you repeat the question?

22 Q. Sure. Have you seen a report from the pathologist at the
23 Northwest Medical Center analyzing this mesh in the same
24 manner that you did?

25 A. As I stated, this is the report and they received,

—IAKOVLEV - CROSS - THOMAS—

1 documented, and sent it to Steelgate. They didn't perform
2 analysis.

3 Q. Thank you. Now, when the surgeon removed the mesh in
4 July, 2012, it was placed in formalin; correct?

5 A. That's correct.

6 Q. And when the surgeon removed the mesh during this
7 procedure, he used heat to remove the mesh?

8 A. By the examining of the specimen, it was not enough
9 cautery artifact there. If it was used, it was used really
10 gently because the beauty of the microscopy is I can see the
11 changes which can be caused by heat or by fixation. So, for
12 that specific specimen I did not see extensive cautery
13 artifact.

14 Q. Did you see any evidence of heat?

15 A. Not to a degree which would prevent me from analysis.

16 Q. Okay. Now, after the removal of this mesh explant,
17 you've already testified it was -- you had seven pieces and
18 you showed the jury a picture of that. Correct?

19 A. This is not correct. I had four pieces.

20 Q. I'm sorry. But you know that there were seven pieces
21 from the explant?

22 A. It's not on the boards.

23 Q. Oh, I'm sorry. No wonder I can't find it.

24 A. Are you looking for this photograph?

25 Q. Thank you. Have you -- you know there were seven pieces

—IAKOVLEV - CROSS - THOMAS—

1 removed?

2 A. Yes, I do.

3 Q. And you know three of those pieces were sent to an
4 analytical chemist to analyze?

5 A. I don't know that.

6 Q. You don't know that. Okay. You're not an analytical
7 chemist, are you?

8 A. No.

9 Q. And you know that analytical chemists have tools
10 available to them to analyze chemically what's in that mesh,
11 don't you?

12 A. That's what analytical chemists do.

13 Q. But you've not done that in your work in this case as any
14 analytical chemistry to determine what is chemically present
15 in the mesh. True?

16 A. This is not completely true. I did my histological
17 analysis using my histological tools to analyze what is
18 chemical composition.

19 Q. All right. So, to the extent that you used the dyes as
20 you talked about on your direct examination, that's chemistry
21 as far as you're concerned?

22 A. Yes.

23 Q. All right.

24 A. Dye is a chemical.

25 Q. Is that the extent of the chemistry that you did?

—IAKOVLEV - CROSS - THOMAS—

1 A. Both polarizing light and dyes. These are histological
2 tools.

3 Q. Okay. You received the four samples that you just showed
4 the jury. You talked about on direct examination this
5 formalin solution. Correct?

6 A. That's correct.

7 Q. And the tissue samples before they were placed in
8 formalin were covered in tissue; correct? The mesh had tissue
9 on it.

10 A. Well, the pieces came as mesh with tissue together.

11 Q. Right. And do you understand that that's the explant as
12 removed from Ms. Bellew?

13 A. Yes.

14 Q. And that's mesh with tissue on it; correct?

15 A. That's correct.

16 Q. And then it was placed in the formalin; correct?

17 A. That's correct.

18 Q. And you understand that formalin and tissue cross-links;
19 correct?

20 A. Repeat, please.

21 Q. You understand that formalin solution cross-links with
22 proteins that are in the tissue; correct?

23 A. That's correct. That's how it preserves tissue.

24 Q. Can you tell the jury the chemical reaction that occurs
25 when formalin cross-links with the tissues?

—IAKOVLEV - CROSS - THOMAS—

1 A. Specific details?

2 Q. Yes.

3 A. I don't know specific details. It cross-links, binds
4 proteins together so they cannot be degraded by bacteria.

5 Q. And the formalin fixation is important because it
6 preserves the tissue on the mesh so it won't decay; correct?

7 A. That's correct.

8 Q. And the preservation of the tissue allows the pathologist
9 to study the tissue sample for potential disease; correct?

10 A. That's correct.

11 Q. And the formalin fixation hardens the tissue so it can be
12 sliced into the slides that you've analyzed here today;
13 correct?

14 A. No, this is not correct. Hardening or stiffening of the
15 tissues does occur, but it's not done for that purpose. The
16 purpose of formalin is to preserve tissue. It stiffens to a
17 degree.

18 Q. You agree that the formalin and protein cross-linking
19 stiffens the tissue, don't you?

20 A. That's correct.

21 Q. Now, you made no effort to clean the tissue or the
22 formalin from the mesh before you conducted -- you prepared
23 your slides in this case; correct?

24 A. I didn't understand the question. Did I remove formalin?

25 Q. Did you make any effort to clean the mesh before you did

—IAKOVLEV - CROSS - THOMAS—

1 your slide preparation process? You didn't do that, did you?

2 A. What do you mean "clean"?

3 Q. Did you try to remove any material -- any formalin

4 material from the mesh before you did your slide preparation?

5 A. Formalin is being washed out. The processing works as --

6 the formalin is a water soluble substance. It needs to be

7 washed out of the tissue completely by alcohol. And then when

8 the tissue is completely dehydrated, then it can be processed

9 for dissection. So, formalin is removed. Tissue is not

10 removed. The formalin is removed.

11 Q. It's your testimony that the formalin is removed during

12 the sample preparation process?

13 A. Formalin solution, yes. The cross-linking molecules stay

14 there, but the formalin solution is being removed during

15 preparation.

16 Q. Okay. When you say the cross-linking stays there, the

17 cross-linking is the binding between the formalin and the

18 tissue; correct?

19 A. That's correct.

20 Q. And that remains?

21 A. That remains.

22 Q. Now, let's talk a little bit about the sample preparation

23 process. During this sample preparation process when you send

24 the mesh off to the histology department, that's something the

25 technologists, technicians did. You didn't do. Correct?

—IAKOVLEV - CROSS - THOMAS—

1 A. That's correct.

2 Q. And part of that process is to treat this mesh sample
3 with alcohol?

4 A. That's correct.

5 Q. And the alcohol that you use to treat this sample
6 sometimes causes the tissue to shrink?

7 A. To a degree.

8 Q. And you also treat this mesh sample with a material known
9 as xylene?

10 A. That's correct.

11 Q. And xylene is a solvent; correct?

12 A. Yes.

13 Q. And you know that xylene is a solvent to polypropylene?

14 A. I don't know about that.

15 Q. Okay. You've never analyzed the extent to which
16 polypropylene -- excuse me -- that xylene can act as a solvent
17 on polypropylene; correct?

18 A. I did.

19 Q. You, you --

20 A. I did place new mesh in xylene. It's been sitting for
21 eight months. The mesh didn't change.

22 Q. Have you analyzed that mesh chemically?

23 A. No, not chemically.

24 Q. I want to talk to you for a minute about -- I'll go back
25 to 1910-G. Do you remember talking to the jury about 1910-G?

—IAKOVLEV - CROSS - THOMAS—

1 A. Yes, I do.

2 Q. And this is the image that you described of a
3 polypropylene fiber; correct?

4 A. That's correct.

5 Q. And just to orient the jury a little bit, you talked
6 about this degradation bark?

7 A. That's correct.

8 Q. And that's about five microns thick; correct?

9 A. That's correct.

10 Q. And five microns -- how, how thick is a human hair?
11 About 70 microns?

12 A. That's correct. However, we cannot --

13 Q. Excuse me. I get to ask the questions right now.

14 MR. THOMAS: I'm sorry, Your Honor. Can I move to --

15 THE COURT: Yes. It's sustained.

16 MR. THOMAS: Thank you.

17 BY MR. THOMAS:

18 Q. And, so, this bark that's depicted here is about
19 five microns which is about 1/14th the size of a human
20 hair; correct?

21 A. Yes, but it's pipe-like.

22 Q. Now, Doctor, this is magnified, I think you told the
23 jury, a thousand times?

24 A. About a thousand times.

25 Q. All right. And this non-degraded core is what you have

—IAKOVLEV - CROSS - THOMAS—

1 described as the polypropylene fiber; correct?

2 A. The non-degraded part of polypropylene fiber.

3 Q. All right. Now, we just talked a minute ago about the
4 sample preparation process, and when you use alcohol in the
5 sample preparation process that the tissue sometimes retracts
6 or shrinks.

7 A. That's correct.

8 Q. Now, this white area around the bark on Exhibit G is wax,
9 isn't it?

10 A. In that specific image it's clear space.

11 Q. Clear space?

12 A. What is being washed off.

13 Q. Okay. So, it's, it's -- meaning that during the sample
14 preparation, the tissue got pulled away from what you've
15 described as the bark.

16 A. That's correct.

17 Q. And what causes that to pull away like that? Tell the
18 jury.

19 A. Shrinking of the tissue because during formalin fixation
20 and processing, tissue shrinks slightly. And that's the
21 degree it shrinks.

22 Q. So, all of this area which is in white is open space?

23 A. Yes, that's correct.

24 Q. Now, you understand that the polypropylene fiber is a
25 circle, don't you?

—IAKOVLEV - CROSS - THOMAS—

1 A. Not a circle. It's a solid rod.

2 Q. As you look at this, quote, non-degraded core, as you've
3 labeled it in 1910-G, this should be a circle, shouldn't it?

4 A. This is close to a circle.

5 Q. I'm sorry?

6 A. This is close to a circle. It's a bit oval, but it's
7 close.

8 Q. But it's not a circle, is it?

9 A. It's not a perfect circle. It's close to circle.

10 Q. Now, when we, when we make these slices, or when you make
11 these slices, you use a knife?

12 A. Yeah, a microtome.

13 Q. A microtome?

14 A. That's correct.

15 Q. And you cut these slices that are five microns thick;
16 correct.

17 A. About three to five microns, that's correct.

18 Q. That's thinner than a piece of paper, isn't it?

19 A. Yes.

20 Q. And once you make those slices, you put them in water and
21 then they're transferred onto a slide and adhered to the slide
22 with a material known as Permunt; correct?

23 A. Permunt is poured over to hold the crevices. Yes,
24 that's the process.

25 Q. And Permunt has toluene in it; correct?

—IAKOVLEV - CROSS - THOMAS—

1 A. That's correct.

2 Q. And toluene is -- does not behave well with
3 polypropylene. Do you know that?

4 A. I don't know. As I said, I put one mesh in xylene and it
5 stays intact for several months.

6 Q. But you've not analyzed that chemically, have you?

7 A. No, I didn't.

8 Q. So, we have a white area around the polypropylene, that,
9 that open space; correct?

10 A. That's correct.

11 Q. And we have an oval polypropylene fiber that should be
12 round; correct?

13 A. Well, it's -- on this image it's more close to oval.
14 There are multiple -- I can show you that there are perfect
15 round sections.

16 Q. Okay. And the reason for that is because it may have
17 been cut at an angle; correct?

18 A. With a slight angle. If you can imagine if it's a rod,
19 if you take a tree trunk and angle it slightly, then it
20 becomes oval. To get it real oval you have to tilt it all the
21 way almost parallel to the section. So, in this specific
22 image, the filament was slightly tilted.

23 Q. Okay. So, is it fair for the jury to understand that
24 this slice, 1910-G, is cut at something of an angle as opposed
25 to straight across?

—IAKOVLEV - CROSS - THOMAS—

1 A. At a small angle.

2 Q. And that explains the fact that this non-degraded core
3 appears as an oblong as opposed to a circle?

4 A. That's correct.

5 Q. All right. Now, you agree that non-degraded
6 polypropylene does not stain; correct?

7 A. That's correct.

8 Q. And tell the jury why it doesn't stain.

9 A. Because the structure of polypropylene is solid, so it
10 doesn't have cavities to trap dyes. It's like aluminum. You
11 cannot stain aluminum. To stain aluminum, we need to oxidize
12 it, to build this porous layer of oxidation. And then it can
13 trap dyes, and then we can analyze aluminum parts, all those
14 shiny aluminum parts. It's the same process. It's a layer of
15 porous material on a solid surface.

16 Q. Now, Doctor, isn't it true that typically an H&E stain,
17 hematoxylin and eosin stain leaves their colors by a chemical
18 reaction?

19 A. Not exactly chemical reaction. Most of the dyes -- there
20 are different types of dyes. Most of the dyes are trapped.
21 So, it's not fully chemical reaction when molecules form new
22 molecules. It's more of a trapping or binding of the dye
23 molecules inside the material.

24 Q. Let me ask you this. Do you agree with this statement:
25 That staining is not simply coloring the sections

—IAKOVLEV - CROSS - THOMAS—

1 randomly, but depends on using differences in the chemistry of
2 the tissues to show the various components and different
3 colors. This is most commonly done by using dyes that can
4 bind the tissues in a selective way.

5 Do you agree with that?

6 A. Not entirely. Some stains are not specific. They stain
7 everything. As I said, everything porous will trap those
8 dyes. And some stains are designed specifically for specific
9 components. So, you cannot assume that all stains work the
10 same way. They're different.

11 Q. Let me ask you if you agree with this statement:

12 The binding of dyes to tissues is no different to any
13 other chemical bound, bonding, so the mechanisms rely on the
14 same binding forces that occur in all other organic compounds.
15 The dyes must form some form of bond or link to the tissue or
16 they will simply rinse out of the tissue when the section is
17 washed in another reagent.

18 Do you agree with that?

19 A. That was a long sentence. I can say that there is some
20 process of binding of the dye to the tissue either by chemical
21 or trapping mechanically. But there is a binding of the dye
22 in the tissue or any other material.

23 Q. Well, the H&E stain can be broken down into hematoxylin
24 and eosin; correct?

25 A. That's correct.

—IAKOVLEV - CROSS - THOMAS—

1 Q. And hematoxylin stains blue?

2 A. Yes.

3 Q. And hematoxylin is also a positively charged ion, isn't
4 it?

5 A. That's another way of binding with positive or negative
6 charge.

7 Q. And the hematoxylin, a positive ion, binds with
8 negatively charged substances in the body; correct?

9 A. Yes. However, --

10 Q. Excuse me. And they stain those blue; correct?

11 A. You have a different shade.

12 Q. Is your answer "yes" or "no"? "Can you answer "yes" or
13 "no"?

14 A. I cannot answer "yes" or "no" because it's not black and
15 white. When the hematoxylin is applied to the tissue, it
16 stains all structures. Then you have to differentiate. You
17 have to wash it out. And then there is a second chemical.
18 Then there is water applied.

19 So, it becomes bluer and is being washed from the
20 structures which trap the dye non-specifically. So, only
21 those dyed molecules which are still holding by electrical
22 charge are holding. But those molecules which are just
23 trapped in the pores are being washed away. This is a process
24 of differentiation during staining.

25 Q. And that's exactly my point, Doctor, is that after the

—IAKOVLEV - CROSS - THOMAS—

1 hematoxylin stain is applied, you rinse it with water to rinse
2 out any stain that's just on the sample so that you leave the
3 hematoxylin that is bound with the negatively charged tissue
4 materials.

5 A. To a degree. It's not completely clear. It's still
6 purple if you don't do eosin.

7 COURT REPORTER: Excuse me?

8 THE WITNESS: If you don't -- it's not -- it doesn't
9 wash away completely. There is still purple staining if you
10 do not stain it with eosin. The red color just overwhelms
11 purple on the top of it.

12 Q. And the same thing is true with eosin. Eosin stains
13 pink; correct?

14 A. That's correct.

15 Q. And eosin is negatively charged and binds with positively
16 charged materials in the body; correct?

17 A. As far as I remember, that's the mechanism.

18 Q. Do you know the mechanism?

19 A. I don't remember exactly what happens with eosin, but I
20 think you're right.

21 Q. Okay. Thank you. And do you know what charge
22 polypropylene has?

23 A. No.

24 Q. Polypropylene has no charge, does it?

25 A. I don't know.

—IAKOVLEV - CROSS - THOMAS—

1 Q. And that's why none of these stains bind to
2 polypropylene; correct?

3 A. To non-degradable polypropylene.

4 Q. You agree with me the fact that polypropylene has no
5 charge is the reason why neither hematoxylin or eosin bind to
6 polypropylene; correct?

7 A. I don't know.

8 Q. You don't know. You never studied that issue?

9 A. I see that it doesn't stain when it's not degraded. When
10 it's degraded, it stains.

11 Q. Okay. Now, you have offered the opinion that this is,
12 this degraded, what you call bark is oxidized polypropylene;
13 correct?

14 A. Degraded polypropylene.

15 Q. I think you called it oxidized polypropylene.

16 A. Oxidized polypropylene.

17 Q. And can you tell the jury the chemical structure of
18 oxidized polypropylene?

19 A. No, I cannot.

20 Q. All right. Do you know the positive or negative
21 components of oxidized polypropylene?

22 A. No.

23 Q. Do you know whether there are any materials in oxidized
24 polypropylene for either eosin or hematoxylin to bind?

25 A. Can you repeat the question?

—IAKOVLEV - CROSS - THOMAS—

1 Q. Sure. Are there any chemical components in oxidized
2 polypropylene that would allow either hematoxylin or eosin to
3 bind?

4 A. It doesn't bind to chemical components. It's being
5 trapped in the pores and crevices.

6 Q. It's fair to say, isn't it, Doctor, that you're not an
7 expert in the direct oxidation of polypropylene?

8 A. That's correct.

9 Q. And your opinion is that oxidized polypropylene, this
10 bark, has cracks or crevices in it that retain the stain?

11 A. That's my opinion.

12 Q. And, so, in order for that to retain the stain, that
13 means that this material is going to have to hold the stain
14 even during the washing process during the sample preparation
15 process we talked about; correct?

16 A. That's correct, as long as washing doesn't wash it
17 completely because if you extend washing to a degree when it
18 starts washing, the staining fades.

19 Q. Now, again, you've used a light microscope here that
20 magnifies up to about a thousand times?

21 A. That's correct.

22 Q. And it's your belief that this oxidized polypropylene has
23 cracks in it on the order of ten nanometers?

24 A. So, I measured them --

25 Q. Excuse me. Did you measure Ms. Bellew's mesh?

—IAKOVLEV - CROSS - THOMAS—

1 A. No.

2 Q. You did not?

3 A. Well, if you ask me about cracks, I can tell you what's my
4 opinion about cracks.

5 Q. It's about ten nanometers, isn't it?

6 A. It depends on the crack.

7 Q. Okay.

8 A. Some of them larger, some of them smaller.

9 Q. But you've not, you've not measured any cracks in the
10 bark for Mrs. Bellew, have you?

11 A. No. I have no purpose for that.

12 Q. Now, one micron is about the limit of what you can see by
13 light microscopy, isn't it?

14 A. Or half micron depending how good the lenses are.

15 Q. And it's fair to say that your light microscope is not
16 able to detect any cracks in the degraded polypropylene that
17 would hold this stain; correct?

18 A. Those -- the very small pores and crevices which hold?

19 Q. Yes.

20 A. That's correct. I cannot see that. They are too small.

21 Q. So, this is something that you have just concluded based
22 upon what you believe must be happening in Ms. Bellew's mesh
23 that these cracks or crevices retain this dye that show up on
24 this slide. Correct?

25 A. This is not just conclusion based on this specimen. This

—IAKOVLEV - CROSS - THOMAS—

1 is based on my knowledge, training, and experience and
2 examination of this specimen and many others.

3 Q. Now, Doctor, just so the jury understands, it's your
4 opinion that this polypropylene, Prolene polypropylene -- by
5 the way, you know that Prolene polypropylene has special
6 additives added to it?

7 A. Yes. The polypropylene has antioxidants to prevent
8 degradation. It slows it down but it doesn't stop it.

9 Q. And that's what makes Prolene different from other
10 polypropylene. You know that, don't you?

11 A. You mean other mesh devices?

12 Q. Other, other polypropylene used in mesh. You know that's
13 what makes it different, don't you?

14 A. I do not know the exact difference. I'm not a material
15 scientist.

16 Q. And you know the material that makes up polypropylene,
17 Prolene polypropylene is made here in West Virginia, don't
18 you?

19 A. I don't know.

20 Q. Okay. Now, you could have taken a piece of polypropylene
21 and intentionally oxidized it and then washed it with stains
22 to see if there were, in fact, cracks or crevices that held
23 these dyes, couldn't you?

24 A. Yes, I could.

25 Q. But you didn't do that, did you?

—IAKOVLEV - CROSS - THOMAS—

1 A. It's a work in progress. I put --

2 Q. But you haven't done that for this case?

3 A. It's not finished. For this case, no.

4 Q. Okay. Thank you. And if you had a piece of oxidized
5 polypropylene that you stained and it held dyes, that would
6 support your opinion, wouldn't it?

7 A. That's correct.

8 Q. And you talked before about this formalin control that
9 you did. And, that is, you took a piece of pristine mesh and
10 you put it in formalin so that you could make sure that this
11 sample preparation process didn't damage the polypropylene as
12 it went through the sample preparation process. Correct?

13 A. Formalin fixation and sample preparation process.

14 Q. Okay. When you did -- and that's called a controlled
15 experiment?

16 A. That's correct.

17 Q. And that's so you can control for anything that might go
18 wrong. In the sample preparation process, you want to make
19 sure that doesn't confound what you find in your opinions.
20 Correct?

21 A. That's correct.

22 Q. And when you did your formalin controlled experiment, you
23 did not include tissue in that formalin controlled experiment,
24 did you?

25 A. That's correct. That was the whole purpose.

—IAKOVLEV - CROSS - THOMAS—

1 Q. And you didn't include any human serum in that formalin
2 controlled experiment; correct?

3 A. That's correct. That's the whole purpose, just formalin.

4 Q. And the, the -- you were unable to tell the impact of the
5 cross-linking of formalin and protein on your control in your
6 sample preparation process; correct?

7 A. That's correct. I wanted to avoid all tissue -- all
8 foreign tissue.

9 Q. Now, Doctor, you testified that the Prolift mesh for
10 Ms. Bellew had folds in it; correct?

11 A. Yes.

12 Q. And you don't know whether those folds formed before or
13 after the operation, do you?

14 A. Which operation?

15 Q. The implant operation.

16 A. Some of them were formed during surgery and some of them,
17 smaller wrinkles, during scar contracture.

18 Q. Doctor, do you remember when you gave a deposition in
19 this case in August, 2014?

20 A. Yes.

21 Q. And on Page 155 do you remember being asked the
22 question -- can I have that please -- 155, lines 5 through 11.
23 You were asked the question:

24 "Are you saying that the surgeon put it in and put
25 folds in there at the time it was planted?"

—IAKOVLEV - CROSS - THOMAS—

1 "I don't know how, when they formed, intraoperative,
2 post-operative."

3 Did I read that correctly?

4 A. That's correct.

5 Q. And you agree that Mrs. Bellew did not have a mesh
6 erosion. You agree with that, don't you?

7 A. I can only state what I saw in the specimen.

8 Q. Again, let's turn to your deposition again on Page 166,
9 166, lines 3 through 5.

10 "Question: Well, Mrs. Bellew didn't have an erosion."

11 "Answer: No."

12 Did you give that answer at the time of your
13 deposition?

14 A. Yes. I didn't see it on the specimen.

15 Q. And you testified a lot on direct examination about
16 nerves that you saw on the slides?

17 A. That's correct.

18 Q. And you agree that seeing the nerves in these slides does
19 not tell you that any of the pain mechanisms did, in fact,
20 occur in Mrs. Bellew. You agree with that, don't you?

21 A. No, I don't agree.

22 Q. It's true that the feeling of pain is a subjective
23 complaint of a patient. Do you agree with that?

24 A. That's correct.

25 Q. And in order to find pain, the patient has to tell you

—IAKOVLEV - CROSS - THOMAS—

1 there is pain; is that correct?

2 A. That's correct.

3 Q. Let me direct your attention to Page 172 of your
4 deposition, lines 6 through 13.

5 "Question: But seeing a nerve doesn't tell you that
6 any one of those mechanisms actually did, in fact, occur."

7 Your answer: "Feeling of pain is a subjective
8 sensation of a patient. So, to say there was a pain, it would
9 have to be a patient who tells you that there is a pain.
10 Seeing a nerve in the section, I can only assess a risk of it
11 or possibility."

12 Did I read that correctly?

13 A. That's correct.

14 MR. ANDERSON: Excuse me, Your Honor. I would ask
15 that he read the entire answer by the witness from the
16 deposition. He stopped it off at the middle of his answer.

17 THE COURT: It may be done.

18 BY MR. THOMAS:

19 Q. "For example, on this specific picture, the degree
20 of deformation of these nerves at Page 100 of your
21 report would have a very high probability to be painful.
22 Is it your opinion that those nerves on Page 100 of the
23 report are actually causing her to sense pain?"

24 "My opinion is that these deformation of these nerves
25 carries high degree of probability to cause pain."

—IAKOVLEV - CROSS - THOMAS—

1 "But you can't say when those nerves were formed. You
2 can't say whether those nerves were pre-existing in that
3 manner."

4 Answer: "No."

5 Is that enough?

6 MR. ANDERSON: Yeah.

7 THE WITNESS: That's correct.

8 BY MR. THOMAS:

9 Q. Now, we decided you're not an analytical chemist.
10 You've not consulted with an analytical chemist in this
11 case; correct?

12 A. That's correct.

13 Q. And there are also scientists who look at the material
14 properties of, of implants; correct? Material scientists?

15 A. Yes, there are material scientists.

16 Q. And, and you're not a material scientist?

17 A. No, I'm not.

18 Q. And you've not consulted with a material scientist in
19 your work in this case; correct?

20 A. That's correct.

21 Q. Now, you used a light microscope that magnifies up to a
22 thousand times?

23 A. That's correct.

24 Q. And you're aware of a technology known as Scanning
25 Electron Microscopy, aren't you?

—IAKOVLEV - CROSS - THOMAS—

1 A. That's correct. I use Transmission Electron Microscopy.

2 Q. Okay. But you didn't use Transmission Electron
3 Microscopy in this case; correct?

4 A. No. It's very expensive and time consuming.

5 Q. Okay. And you didn't use Scanning Electron Microscopy in
6 this case; correct?

7 A. No. It's not the standard of care.

8 Q. And you don't think the Scanning Electron Microscopy
9 answers any questions for degradation analysis; is that
10 correct?

11 A. If it's used in the right hands, it can answer some
12 questions.

13 MR. THOMAS: I'm sorry, Your Honor.

14 BY MR. THOMAS:

15 Q. Now, let's talk a little bit about how these
16 stains -- how these slides are prepared. Again, this is
17 something that you asked somebody to do for you?

18 A. Our histotechnologists.

19 Q. And it's routine for you to refer pathology specimens to
20 your histotechnologists to prepare these slides for you to
21 analyze?

22 A. This is a routine procedure. All specimens go through
23 the same routine.

24 Q. And have you studied the procedure that the
25 histotechnologist goes through in order to put this material

—IAKOVLEV - CROSS - THOMAS—

1 first in paraffin?

2 A. I don't understand.

3 Q. Let me, let me help you a minute. Let's bring up
4 Defendant's Exhibit 10493.

5 Let me show you what's been marked as Defendant's
6 Exhibit --

7 MR. THOMAS: I'm sorry. I gave you the wrong one,
8 Ben.

9 Excuse me, Your Honor.

10 BY MR. THOMAS:

11 Q. Doctor, I've handed you what's been marked as
12 Defendant's Exhibit 10493 and ask you if you recognize
13 that as the standard protocol for formalin fixed
14 paraffin embedded tissue at your hospital?

15 A. That's correct. I provided them to you.

16 Q. And this describes the process that your
17 histotechnologists use to put the blue samples into paraffin;
18 correct?

19 A. It's a standard procedure. It's used all over North
20 America.

21 Q. Okay. And if you look --

22 MR. THOMAS: Your Honor, I offer Defendant's Exhibit
23 10493.

24 THE COURT: Without objection.

25 MR. ANDERSON: No objection, Your Honor.

—IAKOVLEV - CROSS - THOMAS—

1 (DEFENDANT'S EXHIBIT 10493 RECEIVED IN EVIDENCE.)

2 BY MR. THOMAS:

3 Q. If we look at Paragraph 3. And this is the process
4 that these mesh explants went through as they were first
5 placed in paraffin before they were cut into slides;
6 correct?

7 A. That's correct.

8 Q. And you see that for 16 hours they were exposed to
9 different levels of ethanol and xylene; correct?

10 A. Correct.

11 Q. Am I right that the slides that you used and you talked
12 about today went through the sample preparation process? Am I
13 correct?

14 A. You are correct.

15 Q. Thank you. And the ethanol baths that we've talked about
16 are what caused the tissues to retract?

17 A. Not just ethanol, but --

18 Q. I'm sorry?

19 A. Not just ethanol, but dehydration through ethanol gives a
20 degree of shrinking, and also formalin.

21 Q. And the point of the ethanol is to remove the water;
22 correct?

23 A. That's correct.

24 Q. And then the xylene is designed to remove the ethanol?

25 A. That's correct.

—IAKOVLEV - CROSS - THOMAS—

1 Q. And the xylene is the solvent?

2 A. That's correct.

3 Q. You know it's inappropriate to put xylene in a
4 polypropylene container? Do you know that?

5 A. I don't know that.

6 Q. Let's go to Paragraph 4, please. "Trim paraffin blocks
7 as necessary and cut at three to ten microns (five microns is
8 commonly used.)"

9 And these are the slides that we talked about; correct?

10 A. Yeah. Those were cut at three microns.

11 Q. Three microns. The slides that you have here?

12 A. Yes, that's correct.

13 Q. Okay. So -- and just so the jury understands, you've
14 testified that this bark is about five microns?

15 A. Yes.

16 Q. So, the, the thickness of this slide magnified a thousand
17 times would be something less than the side of the bark?

18 A. That's correct.

19 Q. Okay. And then you cook the slides in an oven overnight?

20 A. Most of them get dried in 60 degrees.

21 Q. Okay. Centigrade?

22 A. Centigrade, yes.

23 Q. And that's after you apply toluene to it?

24 A. Yes.

25 Q. Do you know the impact of heat, xylene, and toluene on

—IAKOVLEV - CROSS - THOMAS—

1 polypropylene?

2 A. Yes, I do.

3 Q. Have you studied it chemically?

4 A. As I said, I put pristine mesh and subjected it to the
5 same procedures and it didn't degrade.

6 Q. Have you studied it chemically?

7 A. Chemically you mean like a chemical scientist?

8 Q. Analytical chemist.

9 A. I'm not analytical chemist.

10 Q. And you've not asked any analytical chemist to look at
11 that, have you?

12 A. No.

13 Q. Then after the slides are prepared, that's when you stain
14 it; correct?

15 A. That's correct.

16 Q. Doctor, I've handed you a copy of what's been marked as
17 Defendant's Exhibit 10495. Do you recognize that as the
18 protocol sheet for the staining of slides at St. Michael's?

19 A. Yeah. I provided those to you.

20 MR. THOMAS: All right. Your Honor, I move admission
21 of Defendant's Exhibit 10495.

22 MR. ANDERSON: No objection.

23 THE COURT: May be admitted.

24 (DEFENDANT'S EXHIBIT 10495 RECEIVED IN EVIDENCE.)

25 BY MR. THOMAS:

—IAKOVLEV - CROSS - THOMAS—

1 Q. And you note, Doctor, that the first step of this
2 is to put the slide in an oven at 65 degrees Centigrade?

3 A. That's correct.

4 Q. Do you know what temperature that is Fahrenheit?

5 A. That's a difficult question.

6 Q. That's okay.

7 A. Over 100 degrees.

8 Q. Okay. And then it's exposed to three separate baths of
9 xylene?

10 A. That's correct.

11 Q. And then three separate baths of alcohol?

12 A. That's correct.

13 Q. And then you wash it with water?

14 A. Yes. It's being saturated with water. It's the process
15 of re-saturation.

16 Q. Okay. And then you add your dye; correct? The
17 hematoxylin?

18 A. Then it goes to dye, either hematoxylin or anything else.
19 It depends on what staining that I want.

20 Q. Well, this one specifically is for hematoxylin and eosin;
21 correct?

22 A. That's correct.

23 Q. And step nine on this protocol is for hematoxylin;
24 correct?

25 A. Yes. But all steps from one to eight will be the same

—IAKOVLEV - CROSS - THOMAS—

1 for any other stain.

2 Q. And then after the hematoxylin is applied, then you go
3 through a series of definition, water, blue buffer, water, and
4 alcohol; correct?

5 A. That's correct.

6 Q. And that's to wash off any dye that doesn't chemically
7 bind; correct?

8 A. Excessive dye, that's correct.

9 Q. Okay.

10 A. It's not a perfect washing off. There's still some
11 remaining.

12 Q. And the same is true for the next step where you -- in
13 step number 12 -- 16, I'm sorry, where you add the eosin dye;
14 correct?

15 A. That's correct.

16 Q. And then you go through three baths of alcohol and two
17 baths of xylene and then you're done?

18 A. Not yet.

19 Q. Well, in terms of the staining process.

20 A. Xylene is not staining anymore. Xylene is preparation
21 for mounting.

22 Q. Right. But in terms -- then you go to the Permount where
23 you put on the cover slip and you put the Permount in order to
24 seal the tissue into place so you can look at it?

25 A. Yes. With the formalin you can put water in it and

—IAKOVLEV - CROSS - THOMAS—

1 you'll get the same appearance.

2 Q. Okay. But my point is after you apply the eosin, you
3 rinse with alcohol and rinse with xylene; correct?

4 A. That's correct.

5 Q. And the goal there again is to remove any eosin that's
6 not bound to tissue?

7 A. Alcohol, yes; xylene, no.

8 Q. Okay.

9 MR. THOMAS: Your Honor, may I have a minute, please?

10 THE COURT: Yes.

11 (Pause)

12 BY MR. THOMAS:

13 Q. Doctor, do you see live patients in your practice?

14 A. Yes, I do.

15 Q. Okay. Do you counsel or treat patients for dyspareunia?

16 A. No.

17 Q. Do you know that there are differences among people,
18 among people that have dyspareunia?

19 A. What do you mean? What differences?

20 Q. Do you know that there are any differences? Do you think
21 dyspareunia is the same in all people?

22 A. No, I don't believe that.

23 Q. Okay. And do you prescribe any kind of medication for
24 pain?

25 A. No, not anymore.

—IAKOVLEV - REDIRECT - ANDERSON—

1 Q. Did you analyze any other tissue removed from Ms. Bellew
2 in this case other than the ones you described, the four?

3 A. No.

4 Q. You didn't examine any of the tissue for the adhesions or
5 the scars, scarring that may have been removed from
6 Ms. Bellew, did you?

7 A. What do you mean? The whole piece was just scar.

8 Q. That's all you -- to the extent that she had other tissue
9 removed at other times for scarring or adhesions, you didn't
10 analyze that tissue, did you?

11 A. No, I didn't analyze anymore tissue. I analyzed this
12 specimen.

13 Q. Did you know that adhesions and scarring can cause pain?

14 A. Yes, it can.

15 MR. THOMAS: That's all I have. Thank you, Doctor.

16 THE COURT: All right. Next witness, please. I'm
17 sorry, redirect. I apologize.

18 (REDIRECT EXAMINATION OF VLADIMIR IAKOVLEV BY MR. ANDERSON:)

19 Q. Let's pick up with that last question. You said that you
20 reviewed the medical records of Ms. Bellew?

21 A. Yes.

22 Q. What happened every time, from the medical records, that
23 Dr. DeHasse removed a chunk of mesh from Ms. Bellew with
24 regard to her pain?

25 A. There was improvement and change in symptoms of pelvic

—IAKOVLEV - REDIRECT - ANDERSON—

1 pain located in the area.

2 Q. And did you review the medical records about this
3 granulation tissue that counsel just mentioned?

4 A. Yes.

5 Q. Did that granulation tissue have any hardened, sclerosed,
6 polypropylene mesh in it?

7 A. No.

8 Q. When they removed that, was there any pain noted in the
9 record related to the granulation tissue?

10 A. There was some discomfort as I understand, but it was
11 transient. It was removed and it cured.

12 Q. Counsel talked a lot about degradation. Even forgetting
13 about degradation, was that the only cause of all the chronic
14 inflammation that you talked about, the fibrotic bridging, the
15 scar plates, the scar encapsulation, the contraction, and the
16 pain in Ms. Bellew?

17 MR. THOMAS: Your Honor, that's beyond the scope.

18 THE COURT: Overruled.

19 BY MR. ANDERSON:

20 Q. Is this the only cause of all the inflammation that
21 we saw in these other images?

22 A. No. This is more of an interesting finding. But the
23 real finding, what I do as a pathologist is scarring,
24 inflammation, nerves, traumatic neuroma.

25 Q. Did you continue to do expensive Scanning Electron

—IAKOVLEV - REDIRECT - ANDERSON—

1 Microscopy or this SEM that he talked about or TEM, this
2 Transmission Electron Microscopy, to be able to come in and
3 tell the jury that that's cracked polypropylene?

4 A. No.

5 Q. Did you need any of that?

6 A. I mean, you can see it clearly.

7 Q. Counsel talked to you a little bit about whether or not
8 you knew that this cracked bark was polypropylene. Do you
9 recall that part of your testimony? Do you recall that part
10 of your testimony?

11 A. Yes.

12 Q. If this was protein, would it polarize light?

13 A. Not to that degree. The strongest protein if it's
14 cross-linked with formalin, in this image you see the darkness
15 of it.

16 Q. So, if this was protein, would it glow bright purple like
17 that?

18 A. I have not seen anything in the human body that rises to
19 that degree. The only object naturally occurring to the body
20 to this degree is crystals. That's uric acid crystals or
21 pyrophosphate crystals. That's how we diagnose.

22 Some cell samples also polarize like this. I performed
23 calcium stain. I checked for it because calcium will be
24 brittle and won't polarize. In this calcium stain it was
25 negative. This material doesn't contain any calcium.

—IAKOVLEV - REDIRECT - ANDERSON—

1 Q. Another question for you, Doctor. You were asked a
2 number of questions about these protocols about xylene,
3 hexylene, benzine, a number of things off these documents by
4 counsel. Do you remember being asked questions about that?

5 A. That's correct.

6 Q. Did you follow standard operating procedures used by
7 pathologists all across North America when you prepared these?

8 A. Yes.

9 Q. Would any of these things that counsel listed off and put
10 up there for the jury, xylene, alcohol, hematoxylin, blue
11 buffer, 95 percent alcohol, does that have anything to do with
12 the scarring that we see in Plaintiff's Exhibit 1910-DD?

13 A. No. You cannot make nerves grow into the mesh. You
14 cannot make scar grow into the mesh. It only happens in the
15 body. The only thing which can do it is human tissue, again
16 growing the mesh, formed scars around it, formed inflammation
17 around it, and deformed nerves.

18 Q. Do you need to be a material scientist to tell the jury
19 that?

20 A. No, because this is my science. This is what I was
21 trained to do.

22 MR. ANDERSON: No further questions.

23 THE COURT: All right. May the witness be excused?

24 MR. THOMAS: Yes, Your Honor.

25 THE COURT: All right.

—LUCENTE - DIRECT BY VIDEO—

1 Thank you, Doctor.

2 Call your next witness.

3 MR. SLATER: Thank you, Your Honor.

4 Your Honor, we now call -- it's a brief video --
5 Dr. Vincent Lucente.

6 THE COURT: Ladies and gentlemen, we will have
7 testimony by videotape. Remember, this testimony was taken
8 under oath and is to be treated by you in the same way and
9 evaluated by you in the same way as testimony presented here
10 in open court.

11 (The videotaped direct testimony of Vincent Lucente
12 was played from 11:47 a.m. until 11:50 a.m.)

13 MR. SLATER: Our next witness, Your Honor, would take
14 about 20 minutes, so it's up to the Court. We tried to time
15 it. We were estimating. So, we could -- we're happy to play
16 it if you want to go over about eight or nine minutes past
17 12:00. Otherwise, it's up to the Court, Your Honor. That's
18 the one we have cued up and ready to go.

19 THE COURT: It's 11:50. We'll take lunch and come
20 back at 12:50. Don't discuss the case among yourselves or
21 permit anyone to discuss it with you or in your presence.
22 Don't use any digital device, read anything, listen to
23 anything, or watch anything about the case. Have a great
24 lunch.

25 Court's in recess until 12:50.

1 (Luncheon recess taken at 11:50 a.m.)

2 (The Jury entered the courtroom at 12:54 p.m.)

3 THE OFFICER: All rise.

4 THE COURT: Good afternoon. Do you think we need to
5 put a regular chair back up there for the witness?

6 THE DEPUTY CLERK: Well, do you want the regular
7 chair back up there for the witness?

8 THE COURT: It's up to --

9 MR. ANDERSON: I'm happy to do it, Judge.

10 THE COURT: Well, it doesn't really matter to me. It
11 just seems like it's easier to sit in than the straight chair.
12 We can do it on the break.

13 MR. ANDERSON: Okay. Sorry.

14 THE COURT: All right. Call your next witness.
15 Yes, sir?

16 MR. THOMAS: Thank you, Your Honor. I neglected to
17 move into evidence defendants' Exhibit 10041 under
18 Dr. Iakovlev's testimony. I do that now.

19 THE COURT: I neglected to admit it. I'll remedy
20 that now.

21 MR. ANDERSON: No objection, Your Honor.

22 THE DEPUTY CLERK: Thank you.

23 MR. THOMAS: Thank you, Your Honor.

24 (DEFENDANTS' EXHIBIT D-10041 WAS RECEIVED IN EVIDENCE.)

25 THE COURT: Mr. Slater?

1 MR. SLATER: Thank you very much, Your Honor. We now
2 call by video Scott Ciarrocca, project leader, the Prolift
3 project, Your Honor.

4 THE COURT: All right. Ladies and gentlemen, a
5 witness by video deposition. Treat the testimony and evaluate
6 it in the same way you would live testimony in court.

7 (The videotaped direct testimony of Scott Ciarrocca
8 was played from 12:56 p.m. to 1:19 p.m.)

9 MR. SLATER: Your Honor, that's all the testimony of
10 Scott Ciarrocca.

11 Plaintiffs will offer into evidence P-2137, P-0968,
12 P-0368, P-0975, and I think we are going to also be moving the
13 clip reports -- we are going to hold the clip reports. I
14 think they should be marked as an exhibit number, I think, so
15 I'm going to offer these documents and we will reconcile the
16 clip reports at a break.

17 THE COURT: Is there an objection?

18 MR. THOMAS: They just gave them to me, Your Honor.
19 I'm sorry. Let me look at them real quickly. 975, 2137, 968
20 and 368?

21 MR. SLATER: Yes.

22 MR. THOMAS: No objection, Your Honor.

23 THE COURT: Exhibits may be received in evidence.

24 MR. SLATER: Thank you, Your Honor.

25 (PLAINTIFF EXHIBITS P-2137, P-0968, P-0368, AND P-0975 WERE

1 RECEIVED IN EVIDENCE.)

2 THE COURT: Is there cross-examination?

3 MR. THOMAS: We reserve cross-examination, Your
4 Honor.

5 THE COURT: Ladies and gentlemen, the defendants have
6 chosen to wait until their case to take testimony from this
7 witness, if they decide to.

8 Witness?

9 MR. SLATER: Yes, Your Honor. We now call Sean
10 O'Bryan who was the regulatory affairs project leader for the
11 Prolift project, Your Honor.

12 (The videotaped direct testimony of Sean O'Bryan was
13 played from 1:21 p.m. to 1:39 p.m.)

14 MR. SLATER: That's the direct testimony, Your Honor.
15 Plaintiffs will offer into evidence P-0980, P-1010,
16 P-2-112, and P-0678.

17 THE COURT: May be received.

18 (PLAINTIFF EXHIBITS P-0980, P-1010, P-2-112, and P-0678 WERE
19 RECEIVED IN EVIDENCE.)

20 THE COURT: Cross-examination?

21 MR. SLATER: I believe so, Your Honor.

22 MS. JONES: We do, Your Honor.

23 THE COURT: All right.

24 (The videotaped cross-examination testimony of Sean
25 O'Bryan was played from 1:39 p.m. to 1:47 p.m.)

1 MS. JONES: That concludes the cross-examination.

2 THE COURT: Is there redirect?

3 MR. SLATER: There is a brief redirect, Your Honor.

4 THE COURT: All right.

5 (The videotaped redirect testimony of Sean O'Bryan
6 was played from 1:47 p.m. to 1:48 p.m.)

7 THE COURT: All right. Call your next witness.

8 MR. SLATER: Your Honor, we call Charlotte Owens who
9 was the worldwide medical director at the time of the launch
10 of the Prolift.

11 THE COURT: Is that by video?

12 MR. SLATER: Yes, it is.

13 THE COURT: Same instruction. Is that adequate?

14 MR. SLATER: Everyone was invited; no one wanted to
15 come.

16 THE COURT: No, I want to make it clear that for
17 reasons, some of which I explained to you, including the power
18 of subpoena, these people are not here, but this testimony was
19 taken under oath and you're to consider it the same as any
20 other testimony. It's just a little harder to watch.

21 MR. SLATER: Thank you, Your Honor.

22 (The videotaped direct testimony of Charlotte Owens
23 was played from 1:49 p.m. to 2:15 p.m.)

24 MR. SLATER: Your Honor, that's the direct.

25 Plaintiff offers Exhibit P-1545, P-2112, P-1010,

1 P-0971, P-1507, as exhibits, and for learned treatises,
2 P-2880.

3 THE COURT: Is there objection?

4 MR. THOMAS: No objection, Your Honor.

5 THE COURT: May be received, exhibits as evidence and
6 the learned treatise as a learned treatise.

7 (PLAINTIFF'S EXHIBITS P-1545, P-2112, P-1010, P-0971, AND
8 P-1507 WERE RECEIVED IN EVIDENCE, AND P-2880 AS LEARNED
9 TREATISE.)

10 THE COURT: Is there cross?

11 MR. THOMAS: Yes, Your Honor, there is.

12 (The videotaped cross-examination testimony of
13 Charlotte Owens was played from 2:16 p.m. to 2:33 p.m.)

14 MR. THOMAS: Your Honor, that concludes the
15 examination of Ms. Owens, Dr. Owens.

16 THE COURT: All right. Any exhibits?

17 MR. THOMAS: Defendants offer defendants' Exhibit
18 25867.

19 THE COURT: Without objection?

20 MR. SLATER: No objection.

21 (DEFENDANTS' EXHIBIT D-25867 WAS RECEIVED IN EVIDENCE.)

22 MR. SLATER: Your Honor, we have -- the next cut is
23 five minutes of the next witness if you want to knock it off.

24 THE COURT: Let's go ahead and do it, and then we
25 will take our afternoon break.

1 MR. SLATER: That would be great for us on
2 scheduling.

3 Our next witness is Kimberly Hunsicker from Ethicon
4 Clinical Affairs. It's about five minutes.

5 THE COURT: All right.

6 (The videotaped direct testimony of Kimberly
7 Hunsicker was played from 2:34 p.m. to 2:39 p.m.)

8 MR. SLATER: That concludes the video.

9 THE COURT: Is there cross?

10 MS. JONES: No, Your Honor.

11 THE COURT: All right, ladies and gentlemen, we'll
12 take our afternoon break. During the break, don't discuss the
13 case, don't communicate about it in any way. I'll call you
14 back in 15 minutes.

15 THE DEPUTY CLERK: Judge, he has an exhibit.

16 THE COURT: Just one minute. You have a matter to --

17 MR. SLATER: I forgot to move the exhibit.

18 THE COURT: It may be admitted.

19 MR. SLATER: P-2864.

20 (PLAINTIFF'S EXHIBIT P-2864 WAS RECEIVED IN EVIDENCE.)

21 (The Jury left the courtroom at 2:40 p.m.)

22 THE COURT: I'll see you in 15 minutes.

23 (A recess was taken at 2:40 p.m.)

24 (The jury entered the courtroom at 2:55 p.m.)

25 THE COURT: On that "please be seated" business if at

1 any time you want to stand up and stretch and so forth, feel
2 free to do that. You don't need to stay glued to your chairs.

3 MR. SLATER: Your Honor, it's going to be Dr. Carol
4 DeHasse. We're just fixing one thing on the computer.

5 THE COURT: All right. The next witness is another
6 video witness. I believe this is the treating physician.

7 MR. ANDERSON: That's correct, Your Honor.

8 THE COURT: All right. Treat the testimony the same
9 as you would any other testimony presented here in the
10 courtroom.

11 You may proceed.

12 MR. AYLSTOCK: Just another minute, Your Honor. I
13 apologize.

14 THE COURT: Sure.

15 MR. SLATER: I think something froze up and we just
16 had to get the documents. I would tell a story about a duck
17 but I don't know any.

18 THE COURT: At least not any you can tell.

19 MR. SLATER: No, that's true.

20 THE COURT: I realize that we're working really hard
21 to take short breaks and keep on trucking. But I've found out
22 over 45 years of doing this that it's a lot easier just to run
23 it on time and keep pressing forward than it is to drag it out
24 over a month. So, at least that's my theory. I'm going to
25 stick to it until somebody tells me different.

—DEHASSE - DIRECT BY VIDEO—

1 (Pause)

2 MR. AYLSTOCK: Your Honor, it appears that we're
3 ready.

4 THE COURT: Here we go.

5 (The videotaped direct testimony of Carol Dehasse was
6 played from 3:02 p.m. until 3:51 p.m.)

7 MR. AYLSTOCK: Your Honor, that concludes the
8 plaintiff's presentation of Dr. Carol DeHasse. I have some
9 exhibits to move in.

10 THE COURT: All right. You may proceed.

11 MR. AYLSTOCK: Your Honor, I'd move into evidence for
12 the record Exhibit P-3404, Exhibit P-2103, Exhibit P-2105,
13 Exhibit P-3396, Exhibit P-1904, Exhibit P-1905, Exhibit
14 P-3405, Exhibit P-1906, Exhibit P-3400, Exhibit P-3401,
15 Exhibit P-2119, Exhibit P-3403, and Exhibit P-3393.

16 MR. THOMAS: I don't have all the ones you had,
17 Bryan. Can I see your stack?

18 MR. AYLSTOCK: Sure.

19 THE COURT: A couple of those have already been
20 admitted.

21 THE CLERK: That's fine.

22 MR. AYLSTOCK: That's okay. I know one of them was a
23 defense exhibit.

24 THE COURT: Before you leave this evening, could you
25 get me the deposition transcripts of the videos we've played

—DEHASSE - CROSS BY VIDEO—

1 so far and get them --

2 MR. SLATER: They're all being marked -- we assumed
3 the Court would want them marked.

4 THE COURT: Yes.

5 MR. SLATER: We're having that done so you'll have
6 them, Your Honor.

7 THE COURT: Okay.

8 MR. AYLSTOCK: Perhaps in the interest of expediency,
9 we can just deal with this at a sidebar.

10 MR. THOMAS: There are several I don't have. I just
11 need to make sure --

12 THE COURT: All right. The motion to admit will be
13 left pending.

14 MR. THOMAS: Thank you, Your Honor.

15 THE COURT: Is there cross?

16 MR. THOMAS: Yes, Your Honor, there is.

17 (The videotaped cross-examination testimony of Carol
18 DeHasse was played from 3:55 p.m. until 4:26 p.m.)

19 MR. THOMAS: Your Honor, could we stop for a minute,
20 please? May I confer with plaintiff's counsel, please?

21 THE COURT: Yes.

22 MR. THOMAS: Your Honor, there was a Q and A omitted
23 from the transcript.

24 THE COURT: Okay. How do you want to fix that? Do
25 you want to do a read?

—DEHASSE - CROSS BY VIDEO—

1 MR. AYLSTOCK: Why don't you just read it, David.

2 MR. THOMAS: If I can go back, --

3 THE COURT: I'll need to explain this to the jury if
4 that's what you're going to do.

5 MR. THOMAS: Okay. The -- I'm sorry. I'm mistaken I
6 guess.

7 THE COURT: All right.

8 MR. THOMAS: I apologize, Your Honor.

9 THE COURT: Okay. Push play.

10 MR. THOMAS: It's in this one too, Your Honor. It is
11 an omission apparently. Do you mind if I just read it in?

12 THE COURT: No. Let me explain to the jury.

13 As I told you, and I know you understand by now, this
14 was all testimony taken earlier and we took out all the
15 lawyering and the judging and have given you edited
16 videotapes.

17 In that process, apparently we have edited out
18 something that we shouldn't have edited out. And instead of
19 going back and trying to find the snippet of tape with the
20 testimony, I am going to ask counsel to simply read the
21 questions that were posed to this witness and to read her
22 answers. And you are to consider that in the same way you
23 would as if she were testifying from the witness stand.

24 Do you understand?

25 (All jurors indicated an affirmative response.)

—DEHASSE - CROSS BY VIDEO—

1 THE COURT: Are we in agreement, counsel?

2 MR. AYLSTOCK: We are, Your Honor. No objection.

3 THE COURT: You may proceed.

4 MR. THOMAS: With permission, I'd like to ask a
5 couple of questions ahead of time to put it in context. Is
6 that all right?

7 THE COURT: Yes.

8 MR. AYLSTOCK: Sure.

9 MR. THOMAS: Beginning at 463, line 25:

10 "She's just -- she's having some spotting, flashes,
11 difficulty sleeping, and mood lability.

12 Answer: Yes.

13 Question: Needs HRT.

14 Answer: Hormone replacement therapy.

15 Question: All right. Was it at this point you're
16 still prescribing the estrogen cream?

17 Answer: Yes.

18 Question: And that would have been important to use?

19 Answer: Yes."

20 That's all, Your Honor.

21 MR. AYLSTOCK: Thank you.

22 THE COURT: All right. Let's continue with the
23 video.

24 (The videotaped cross-examination testimony of Carol
25 DeHasse was resumed and played from 4:29 p.m. until 4:49 p.m.)

1 MR. THOMAS: Your Honor, I've had a chance to review
2 the exhibits tendered by plaintiff at the close of their
3 evidence and we have no objection to the exhibits that they
4 tendered.

5 Defendants offer Defendant's 10141, 10140, 10135, and
6 10116 and ask that those be received into evidence.

7 MR. AYLSTOCK: I just haven't seen them, Your Honor.
8 I'm sure it's fine.

9 MR. THOMAS: In addition, Your Honor, in the course
10 of the examination of Dr. DeHasse, she identified and actually
11 brought with her to the deposition a different patient
12 brochure.

13 MR. AYLSTOCK: Your Honor, could we, could we do this
14 at the sidebar? This is --

15 THE COURT: Yes.

16 MR. THOMAS: We can do it later if you like.

17 THE COURT: We can do it now.

18 MR. AYLSTOCK: There's no redirect.

19 MR. THOMAS: Okay, perhaps now.

20 THE COURT: Let's do it now.

21 (The following occurred at sidebar:)

22 THE COURT: All right, sir.

23 MR. THOMAS: Your Honor, during the deposition of Dr.
24 DeHasse you heard testimony about the 2008 patient brochure
25 that Dr. DeHasse brought with her to the deposition and she

1 was questioned about that. And the questions about it related
2 to whether the 2008 brochure or the 2006 brochure was the one
3 reviewed by the plaintiff in the case.

4 THE COURT: Uh-huh.

5 MR. THOMAS: And the testimony from the doctor is --
6 although she brought it with her, she could not be sure which
7 brochure that Ms. Bellew saw. And I think it's only fair for
8 the jury to have the benefit of that brochure as they
9 deliberate as well.

10 MR. AYLSTOCK: Your Honor, I don't believe that any
11 testimony from Dr. DeHasse was designated or played about the
12 2008 brochure. She was simply asked: Which one? Does she
13 recall? And she said, no, she does not. The testimony in
14 this case from Mrs. Bellew will be she saw the 2006 brochure
15 and only the 2006 brochure. So, --

16 THE COURT: All right. Here's what I remember. She
17 was asked and, by Ethicon's lawyer, "Isn't it more likely,
18 given the time frame, that she was given the 2008 brochure?"

19 MR. THOMAS: Exactly right.

20 THE COURT: And she said, "Not necessarily. It just
21 kind of depends. They just --" from an earlier answer she
22 said, "They just add them to the stack." And without
23 remembering the exact words, she said, "I just can't say which
24 brochure she got."

25 Now, I know from reading the papers that she's going

1 to say she had the 2006. But I didn't see anything where you
2 asked this witness about the 2008 brochure or any discussion
3 about it other than did she or did she not give it to her and
4 she said she didn't know.

5 I'm sure in your case you may find a way to get the
6 2008 brochure in, but I'm not going to let it in right now.

7 MR. AYLSTOCK: Thank you, Your Honor.

8 MR. THOMAS: Thank you, Your Honor.

9 (Sidebar concluded.)

10 THE COURT: Ladies and gentlemen, we're going to keep
11 working. It's going to be about 13 minutes. We're going to
12 keep working. You'll be glad.

13 MR. AYLSTOCK: Your Honor, the plaintiff's exhibits
14 identified in conjunction with Dr. DeHasse, are those exhibits
15 admitted?

16 THE COURT: They are.

17 MR. AYLSTOCK: Thank you, Your Honor.

18 THE COURT: As are the ones offered by the defendant
19 just now.

20 (PLAINTIFF'S EXHIBITS P-3404, P2103, P-2105, P-3396,
21 P-1904, P-1905, P-3405, P-1906, P-3400, P-3401, P-2119,
22 P-3403, and P-3393 RECEIVED IN EVIDENCE.)

23 (DEFENDANT'S EXHIBITS 10141, 10140, 10135, AND 10116
24 RECEIVED IN EVIDENCE.)

25 THE COURT: Go ahead and start the television.

—LISA - DIRECT BY VIDEO—

1 MR. SLATER: Okay, Your Honor.

2 Your Honor, through the mayhem, plaintiff calls Bryan
3 Lisa who worked at Ethicon Regulatory Affairs during the
4 relevant time period.

5 THE COURT: All right.

6 (The videotaped direct examination testimony of Bryan
7 Lisa was played from 4:54 p.m. until 5:07 p.m.)

8 MR. AYLSTOCK: Your Honor, that concludes the
9 testimony of Mr. Bryan Lisa.

10 THE COURT: I understand there's no cross.

11 MR. SLATER: There's no cross, Your Honor, and we
12 have a few exhibits to move and we have those transcripts for
13 you as well.

14 We move from this deposition P-160, P-0366, and
15 P-0462, although I think we should confer. There may be a
16 couple things that we may want to work on, some redactions I
17 just noticed just in case.

18 MS. JONES: Your Honor, we would have objections to
19 the P-462 and P-366 that we would need to take up.

20 THE COURT: All right. Why don't I let the jury go
21 home and let's straighten this out.

22 MR. SLATER: No problem.

23 THE COURT: Ladies and gentlemen of the jury, we'll
24 be in recess, be adjourned for the day and start again at 9:00
25 in the morning. The roads are icy. So, if you live very far

1 away, you probably ought to spend another night in the warmth
2 of your hotel room. It's up to you entirely.

3 You are serving as jurors, a mandatory duty of
4 citizenship, but I am not adding the additional condition that
5 you be confined. So, it will be entirely up to your good
6 judgment what you do. But I'll expect to see all your shining
7 faces here tomorrow at 9:00. Have a nice evening.

8 Don't discuss the case or communicate about the case
9 in any way, shape, or form.

10 (The jury left the courtroom at 5:09 p.m.)

11 THE COURT: Of course as you're rattling off those
12 numbers, I have not the slightest idea what you're talking
13 about. So, you're going to have to tie a number to a subject
14 matter or I won't be able to figure it out.

15 MS. JONES: May I address our objections because I
16 think it's fairly simple and Your Honor may wish to look at
17 the documents?

18 I object to P-462 about which Mr. Lisa was
19 questioned. Plaintiffs have identified some of it. But it
20 is, in fact, a letter to the -- I'm sorry -- the redacted
21 portions of it. It is, in fact, a letter to the FDA. It is
22 strictly a regulatory document.

23 And under those circumstances and under Your Honor's
24 rulings thus far, I think it would be inappropriate to be
25 admitted.

1 THE COURT: I had some problem with the testimony.

2 MS. JONES: Well, so did I.

3 THE COURT: But it's -- I adopted the rulings. I'll
4 look at that.

5 MS. JONES: The second thing, Your Honor, is a
6 similar document, P-366, which is also a regulatory document.
7 It is addressed "To Whom It May Concern" but it's provided
8 that it can be released to the following countries. And, so,
9 it actually is a foreign regulatory document that --

10 THE COURT: Can I -- let's go off the record so I can
11 ask a few silly questions.

12 (Discussion off the record after which the following
13 occurred:)

14 MS. JONES: I have no objection to 160.

15 THE COURT: 160 is received.

16 (PLAINTIFF'S EXHIBIT P-160 RECEIVED IN EVIDENCE.)

17 MR. SLATER: I also have with Dr. Elliott and we
18 referenced it several times -- I thought I had moved it.
19 Apparently I may not have. It's P-1593. It's a document --
20 the professional education dec used at the time Dr. DeHasse
21 said she was trained. We offer that into evidence. It's
22 already been utilized in the testimony with Dr. Elliott
23 several times.

24 MS. JONES: I don't have any objection. I think
25 that -- my recollection was that we had agreed that a couple

1 of pages would be, but I anticipate that it will all be
2 ultimately.

3 THE COURT: That's fine.

4 MR. SLATER: Thank you.

5 THE COURT: It's got a number on it?

6 MR. SLATER: It does and it was utilized.

7 THE COURT: May be admitted.

8 (PLAINTIFF'S EXHIBIT P-1593 RECEIVED IN EVIDENCE.)

9 MR. SLATER: For the record, I could read in the
10 exhibit numbers and we have the transcript excerpts for you,
11 Your Honor, on all the deposition designations save I told --
12 I looked around because we traded people, so Mr. Lisa's is
13 being stamped right now. But I have them ready to read the
14 numbers for you, Your Honor, and hand them up.

15 THE COURT: The deposition exhibits as played today
16 is what you're going to present now?

17 MR. SLATER: These are the -- I have them all.

18 THE COURT: Or yesterday or all of the day.

19 MR. SLATER: These are all of the scripts for what
20 was actually played to the jury, Your Honor.

21 MS. JONES: By the plaintiffs or by --

22 MR. SLATER: By the plaintiffs.

23 MR. AYLSTOCK: And I have a courtesy copy for Your
24 Honor if you'd like them.

25 THE COURT: Okay. They're not exhibits. They're

1 filed.

2 MR. SLATER: They're filed. Okay. Shall I identify
3 them for the record?

4 THE COURT: Yes, please.

5 MR. SLATER: Okay. I'll go through them real quick.

6 Paul Parisi, P-3414; Piet Hinoul, P-3415; Uwe Klinge,
7 P-3416; Gene Kammerer, P-3417; Vincent Lucente, P-3418; Scott
8 Ciarrocca -- that's C-i-a-r-r-o-c-c-a -- P-3419; Sean O'Bryan,
9 P-3420; Charlotte Owens, P-3421; Kimberly Hunsicker, P-3422;
10 Dr. Carol DeHasse, P-3423; Bryan Lisa, P-3425.

11 They're now identified and I have them here for the
12 Court.

13 And my last piece of housekeeping is -- whether it
14 has to be on the record -- this is probably not an
15 on-the-record kind of thing.

16 THE COURT: Okay. These may be filed as exhibits and
17 considered a part of the transcript of the proceedings.

18 MR. SLATER: Thank you, Your Honor.

19 The only other issue I was going to state, counsel
20 asked when we thought we were going to rest based on where we
21 are. We have to look at the timing of how we did today. But
22 we think -- counsel -- based on -- this doesn't have to be for
23 the record frankly. It's up to you.

24 THE COURT: No.

25 (Discussion off the record, after which the following

1 occurred:)

2 MR. THOMAS: Your Honor, we filed, pursuant to the
3 Court's direction, some modifications to the Pre-Trial Order
4 and to the jury instructions.

5 THE COURT: All right. Anybody else got anything
6 like that?

7 MR. ANDERSON: Real quickly, Your Honor, just that
8 Your Honor had earlier -- we admitted Plaintiff's Exhibit 1910
9 during Dr. Iakovlev, but it was subject to, it was subject to
10 just pulling out the particular exhibits that did not have
11 writing on them.

12 And, so, I've met with Mr. Thomas and we've pulled
13 out which ones of those are going to go into the record. That
14 would be Plaintiff's Exhibit 1910-Z. That would be
15 Plaintiff's Exhibit 1910-NN. That would be Plaintiff's
16 Exhibit 1910-BBB. That would be Plaintiff's Exhibit 1910-ZZ.
17 That would be Plaintiff's Exhibit 1910-L. Plaintiff's Exhibit
18 1910-CC, but we have the version that's marked. And, so,
19 we're going to bring you the one tomorrow morning that doesn't
20 have the marking on it. It's the exact same photo and it's
21 one that we put on the record at the very end. But I will
22 replace that for you tomorrow. Would you like it for now and
23 then I replace it or I just keep it?

24 THE CLERK: Sure. That's fine.

25 MR. ANDERSON: All right. And I believe that covers

1 that bit of housekeeping. I ask it be admitted.

2 THE COURT: May be done.

3 MR. ANDERSON: Thank you, Your Honor.

4 (PLAINTIFF'S EXHIBITS 1910-Z, 1910-NN, 1910-BBB,
5 1910-ZZ, 1910-L, 1910-CC RECEIVED IN EVIDENCE.)

6 MR. AYLSTOCK: This doesn't need to be on the record.

7 (Discussion off the record, after which the following
8 occurred:)

9 MR. ANDERSON: I'm so sorry. I missed one.

10 David, I missed one. It was the 1910-PP.

11 MR. THOMAS: No objection.

12 MR. ANDERSON: I ask that it be admitted, Your Honor.

13 THE COURT: May be admitted.

14 MR. THOMAS: No objection, Your Honor.

15 (PLAINTIFF'S EXHIBIT 1910-PP RECEIVED IN EVIDENCE.)

16 MR. ANDERSON: Thank you.

17 THE COURT: Let's stay on the record for a minute.

18 You still are talking in your papers filed, the
19 plaintiffs, about fraud and misrepresentation. Those claims
20 were dismissed.

21 MR. AYLSTOCK: Your Honor, --

22 MR. SLATER: The reason -- if I may, Your Honor.

23 THE COURT: Sure.

24 MR. SLATER: As I had stated at sidebar the other
25 day, we believe that if the jury finds that there were no

1 adequate warnings to the doctor that the learned intermediary
2 defense is gone from the case. And we would -- we're going to
3 hope to convince Your Honor that an instruction could be
4 fashioned that would be contingent on that finding because I
5 know Your Honor relied on the learned intermediary to say
6 there would not be fraud. But we believe that if the jury
7 finds failure to warn because there's a lack of adequate
8 warnings, there is by law in Arizona no learned intermediary
9 defense at that point because it's obviously phrased as if an
10 adequate warning is provided to the doctor, then you don't
11 have to warn the plaintiff.

12 But if they haven't adequately warned the doctor,
13 then they would have had the duty to provide accurate
14 information. They would no longer have that defense anymore,
15 and then fraud would be in play at that point. That's our
16 position.

17 MR. AYLSTOCK: Your Honor, -- I'm sorry, Your Honor.
18 This is Eric Walker. He's writing a responsive brief, so I
19 just wanted to introduce him to Your Honor.

20 MR. WALKER: One of the briefs that Mr. Aylstock
21 referenced is a very short brief we're filing. An Arizona
22 Court of Appeals ruled this year, just a couple months ago,
23 that the learned intermediary doctrine does not apply in
24 Arizona anymore.

25 THE COURT: I read it yesterday afternoon.

1 MR. WALKER: And, so, we're filing a supplemental
2 brief on that. It's very short.

3 THE COURT: Okay. I'm well aware of that case.

4 MR. AYLSTOCK: Thank you, Your Honor.

5 THE COURT: You might also address, while you're at
6 it, if there's anything in that case that changes the, in your
7 opinion, the law of punitive damages in Arizona. Oh, we're
8 going with New Jersey law in this case. Nevermind. I don't
9 care what the punitive damage law is in Arizona.

10 MR. ANDERSON: As you were saying. Right?

11 THE COURT: Yeah. Go ahead and give them that cite
12 now so they can give any response they want to give instead of
13 waiting until the midnight brief. I've read that case and we
14 did a little work on it yesterday. So, I'm aware of it.
15 Actually, it's why I asked whether or not anybody was going to
16 file any additional things.

17 See you later.

18 MR. ANDERSON: Thank you, Judge.

19 MR. AYLSTOCK: Thank you, Your Honor.

20 MR. SLATER: Thank you, Your Honor.

21 MS. JONES: Thank you, Your Honor.

22 (Trial recessed at 5:27 p.m.)

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REPORTERS' CERTIFICATE

Carol Farrell, CRR, RMR, CCP, RSA, RPR, and Lisa A. Cook, RPR, RMR, CRR, FCRR, Official Court Reporters of the United States District Court for the Southern District of West Virginia, do hereby certify that the foregoing is a true and accurate transcript, to the best of our ability, of the proceedings as taken stenographically by and before us at the time, place, and on the date hereinbefore set forth.

/S/ Carol Farrell, CRR, RMR, CCP, RSA, RPR

03/05/2015

Court Reporter

Date

/S/ Lisa A. Cook, RPR, RMR, CRR, FCRR

03/05/2015

Court Reporter

Date